CARDIAC SCIENCE AEDs

G3 *third generation*

Operation and Service Manual

POWERHEART® **AED** G3 *Pro*

automated external defibrillator

CARDIAC SCIENCE

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Cardiac Science Corp. ("Cardiac Science") warrants to the original purchaser that its AEDs and stated battery will be free of any defect in material and workmanship according to the terms and conditions of this Limited Warranty ("Limited Warranty"). For purposes of this Limited Warranty, the original purchaser is deemed to be the original end user of the product purchased. This Limited Warranty is NONTRANSFERABLE and UNASSIGNABLE.

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- Any Cardiac Science product case is opened by unauthorized personnel or if a product is used for an unauthorized purpose.
- Any Cardiac Science product is used in conjunction with incompatible parts or accessories, including but not limited to batteries. Parts and accessories are not compatible if they are not Cardiac Science products or the functional equivalent.

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If your Cardiac Science product is not covered by our Limited Warranty, call us toll free at (888) 466-8686 for advice as to whether we can repair your Cardiac Science product, and for other repair information, including charges. Charges for non-warranty repairs will be assessed and are your responsibility. Upon completion of the repair, the terms and conditions of this Limited Warranty shall apply to such repair or replacement product for a period of 90 days.

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CAUTION

Federal law restricts this device to be sold by or on the order of a physician or practitioner licensed by state law in which he/she practices to use or order the use of the device.

IMPORTANT

Read this Operation and Service Manual carefully. It contains information about your safety and the safety of others. Become familiar with the controls and how to use the AED properly before operating the product.

Cardiac Science AEDs are manufactured by:
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This device may be covered by the following U.S. and foreign patents:
5,792,190, 5,999,493, 5,402,884, 5,579,919, 5,749,902, 5,645,571, 6,029,085, 5,984,102, 5,919,212, 5,891,172, 5,674,266, 5,700,281, 5,891,173, 5,968,080, 6,263,239, 5,797,969, D402,758, D405,754, 5,909,138, 6,173,203, 6,088,616, 5,897,576, 5,955,956, 6,083,246, 6,064,909, 6,038,473, 5,868,794, 6,115,638, 6,366,809, 5,474,574, 6,246,907, 6,289,243, 6,411,846, 6,480,734, EP00756878
Other U.S. and foreign patents pending.

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LIMITED WARRANTY

The Cardiac Science AED Operation and Service Manual and any and all information contained herein do not constitute any warranty as to the Powerheart AED G3 Pro, or any related products in any manner whatsoever. The “Limited Warranty” is shipped with the AED and serves as the sole and exclusive warranty provided by Cardiac Science regarding Cardiac Science AED products.

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Fax: 425.402.2001
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Email: customerservice@cardiacscience.com
internationalsales@cardiacscience.com
techsupport@cardiacscience.com
internationalservice@cardiacscience.com

There is no charge to the customer for a customer support call. Please have the serial and model numbers available when contacting Customer Service. (The serial and model numbers are located on the underside of the Cardiac Science AED.)

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DEFIBRILLATOR TRACKING

Defibrillator manufacturers and distributors are required, under the Safe Medical Devices Act of 1990, to track the location of defibrillators they sell. Please notify Cardiac Science Customer Service in the event that your defibrillator is sold, donated, lost, stolen, exported, destroyed or if it was not purchased directly from Cardiac Science Corp.

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TABLE OF CONTENTS

SECTION 1 - SAFETY

OVERVIEW....7
SAFETY TERMS DEFINITIONS....7
SAFETY ALERT DESCRIPTIONS....8
SYMBOL DESCRIPTIONS....11

SECTION 2 - INTRODUCTION

OVERVIEW....15
AED DESCRIPTION....15
INDICATIONS FOR USE....15
RHYTHMx AED ECG ANALYSIS ALGORITHM....16
RESCUE PROTOCOL....18
STAR BIPHASIC WAVEFORM....18
STAR BIPHASIC ENERGY PROTOCOLS FOR POWERHEART AED G3 PRO....18
OPERATOR TRAINING REQUIREMENTS....20

SECTION 3 - GETTING STARTED

OVERVIEW....21
UNPACKING AND INSPECTING....21
AED PARTS....22
AED MODES....23
POWERHEART AED G3 PRO BATTERIES....24
RECHARGEABLE BATTERY AND CHARGER....26
DEFIBRILLATION PADS (ELECTRODES)....28
AED INDICATORS....29
SETTING THE AED INTERNAL CLOCK....33
VOICE PROMPTS AND TEXT DISPLAY....33

SECTION 4 - INSTRUCTIONS FOR USE

OVERVIEW....37
OPERATING MODES....37
STEP 1: ASSESSMENT AND PAD PLACEMENT....38
STEP 2: ECG ANALYSIS (AED MODE)....39
STEP 3: SHOCK DELIVERY AND CPR MODE (AED MODE)....40
STEP 4: POST RESCUE....40

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SECTION 4 - INSTRUCTIONS FOR USE (CONT'D)

USING MANUAL OVERRIDE (MANUAL MODE) 41
ECG DISPLAY FOR ONGOING MONITORING (ECG MONITORING MODE) 42
Z-BAR INDICATOR 43
WARNINGS 44

SECTION 5 - DATA MANAGEMENT

OVERVIEW 45
RECORDING RESCUE DATA 45
REVIEWING RESCUE DATA 45
MULTIPLE RESCUE FUNCTIONALITY 46

SECTION 6 - MAINTENANCE & TROUBLESHOOTING

OVERVIEW 47
SELF-TESTS 47
INDICATOR TROUBLESHOOTING TABLE 48
SCHEDULED MAINTENANCE 49
AUTHORIZED REPAIR SERVICE 50
FREQUENTLY ASKED QUESTIONS 51

SECTION 7 - TECHNICAL DATA

OVERVIEW 53
PARAMETERS 53
SAFETY AND PERFORMANCE STANDARDS 56
STAR BIPHASIC WAVEFORM 59
RHYTHMx ECG ANALYSIS PERFORMANCE 61

SECTION 8 - MDLINK

OVERVIEW 63
MDLINK INSTALLATION 64
ESTABLISH CONNECTION FROM THE AED TO THE COMPUTER 65
SELECTABLE OPTIONS PARAMETERS 68
COMMAND BUTTONS 71

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SECTION 1 – SAFETY

OVERVIEW

This section presents safety information to guard against injury to persons and damage to the Powerheart AED G3 Pro.

TOPIC	PAGE #
Safety Terms Definitions	7
Safety Alert Descriptions	8
Symbol Descriptions	11

SAFETY TERMS DEFINITIONS

BEFORE OPERATING THE POWERHEART AED G3 PRO

Become familiar with the various safety alerts in this section.

Safety alerts identify potential hazards using symbols and words to explain what could potentially harm you, the patient, or the Powerheart AED G3 Pro.

SAFETY TERMS AND DEFINITIONS

The triangle attention symbol shown below, left, identifies the potential hazard categories. The definition of each category is as follows:

DANGER: This alert identifies hazards that will cause serious personal injury or death.

WARNING: This alert identifies hazards that may cause serious personal injury or death.

CAUTION: This alert identifies hazards that may cause minor personal injury, product damage, or property damage.

PRODUCT REFERENCES

For purposes of retaining simple, clear instructions in this manual, note the product references used. Features, specifications, operating instructions and maintenance on the Powerheart AED G3 Pro will be referred to as “AED” or “device”.

Defibrillation electrodes will be referred to as “defibrillation pads” or “pads”, ECG monitoring electrodes will be referred to as “ECG monitoring electrodes” or “ECG electrodes”.

Features and specifications vary, so please read this manual carefully. For questions regarding the differing features among Cardiac Science AEDs, please contact Customer Service (see page 4).

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SAFETY ALERT DESCRIPTIONS

The following is a list of Cardiac Science AED safety alerts that appear in this section and throughout this manual. You must read, understand, and heed these safety alerts before attempting to operate the AED.

DANGER: Fire and Explosion Hazard
Exercise caution when operating the AED close to flammable gases (including concentrated oxygen) to avoid possible explosion or fire hazard.

WARNING: Shock Hazard
Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation pads and ECG electrodes clear of other electrodes or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

WARNING: Shock and Possible Equipment Damage
Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

WARNING: Battery (P/N: 9145) is **NOT** Rechargeable
Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard. **Only battery (P/N: 9144) is rechargeable.**

WARNING: Shock Hazard
Do not disassemble the AED! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to Cardiac Science authorized service personnel.

WARNING: Battery Serviceability
Do not disassemble the battery! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to authorized service personnel.

CAUTION: Temperature Extremes
Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED; if the daily self-test determines environmental conditions outside of the AED's operating parameters, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Section 7 – Technical Data, Parameters, Operation and Standby Conditions.

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CAUTION: Lithium Sulfur Dioxide Battery
Pressurized contents: Never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

CAUTION: Lithium-ion Battery
Never short circuit, puncture, deform, or expose to temperatures above 65°C (149°F).

CAUTION: Battery Disposal
Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

CAUTION: Use only Approved Equipment
The Rechargeable battery is made solely for Powerheart AED G3 Pro, and is NOT to be used with any other AED models. Using batteries, pads, cables, or optional equipment other than those approved by the manufacturer may cause the AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance
Using defibrillation pads that are damaged or expired may result in improper AED performance.

CAUTION: Possible Radio Frequency (RF) Susceptibility
RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 2 meters of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.

CAUTION: Possible Interference with Implanted Pacemaker
Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection, however with some pacemakers the AED may not advise a defibrillation shock.[1]

Placing Defibrillation Pads:

- Do not place the defibrillation pads directly over an implanted device.
- Place the defibrillation pads at least one inch from any implanted device.

[1] *Cummins, R., ed., Advanced Cardiac Life Support; AHA (1994): Ch. 4.*

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⚠ ***CAUTION:*** Moving the Patient During a Rescue
During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

⚠ ***CAUTION:*** Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

⚠ ***CAUTION:*** The AED is programmed with software that has been tested to work with versions of Rescuelink and MDLink that are included with the AED. When using older version of Rescuelink and MDLink are used to communicate with this AED, there may be features described in this manual that are not available to be used. Also, when communicating with an older AED with the version of Rescuelink and MDLink included with this new AED there may be features described in this manual that cannot be edited. The software in most cases will give an error message when incompatibilities occur.

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SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the AED, or on its optional components. Some of the symbols represent standards and compliances associated with the AED and its use.

Dangerous Voltage: The defibrillator output has high voltage and can present a shock hazard. Please read and understand all safety alerts in this manual before attempting to operate the AED.

Attention!: Identifies important information in this manual, on the AED, or on its component parts regarding the safe and proper use of the AED.

Defibrillator Proof Type BF Equipment: The AED, when connected to the patient's chest by the defibrillation pads, can withstand the effects of an externally applied defibrillation shock.

CE Mark: This equipment conforms to essential requirements of the Medical Device Directive 93/42/EEC.

IP24 The AED is protected against the effects of splashing water in accordance with IEC 60529.

Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

International symbol for ON. Open the lid to turn on the AED.

Open the lid to turn ON the AED.

Indicates the AED battery status. The illuminated areas indicate the remaining battery capacity.

1. Position of defibrillation pads on the chest of patient.
2. When pads on screen are flashing, check defibrillation pads. The defibrillation pads are missing, not connected or have compromised functionality.

Indicates AED requires maintenance by authorized service personnel.

When the **SHOCK** indicator is lit, push this button to deliver a defibrillation shock.

When pushed and confirmed, activates manual mode.

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SYMBOL DESCRIPTIONS (CONT.)

The Z-Bar provides a relative visual indicator of the total transthoracic impedance between the two defibrillation pads.

A red indicator with a BLACK X means the AED requires operator attention or maintenance, and is not RescueReady. This symbol will be referred to as **RED** in the remainder of this manual.

A green indicator without a BLACK X means the AED is RescueReady. This symbol will be referred to as **GREEN** in the remainder of this manual.

Use defibrillation pads by this date.

Date of manufacture, year and month.

Date of factory recertification (R).

Latex free.

Disposable. Single patient use only.

Tear here to open.

Do not recharge battery.

For use by or on the order of a Physician, or persons licensed by state law.

Dispose of properly in accordance with all state, province, and country regulations.

Do not incinerate or expose to open flame.

Explosion Hazard: Do not use in the presence of a flammable gas, including concentrated oxygen.

Upper and lower temperature limits.

Device model number, battery model number.

Lot number

Default start-up screen.

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Lithium sulfur dioxide

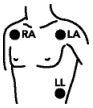
Additional information is provided in the AED Operation and Service Manual.

Points to important information regarding the use of the AED.

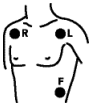
Lift here

Manufacturer

Authorized European Representative



Indicates placement of ECG leads and electrodes, AHA.



Indicates placement of ECG leads and electrodes, IEC.

Indicates that the Manual Override function has been disabled.

C-UL US Classification Mark: indicates compliance with US and Canadian safety requirements.

GS Mark: indicates compliance with German safety requirements.

Lithium Ion

Rechargeable Battery

Charge LED: Solid yellow indicates battery charging, blinking yellow indicates charging error.

Battery Capacity: Indicates the AED battery status. The illuminated areas indicate the remaining battery capacity when the test button is pressed.

Test Button: Push to view battery capacity

Symbol for the marking of electrical and electronic equipment that must be recycled.

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SECTION 2 – INTRODUCTION

OVERVIEW

This section presents information about the AED, its use, and the training requirements for operation.

Topic	Page #
AED Description	15
Indications for Use	15
RHYTHMx AED ECG Analysis Algorithm	16
Rescue Protocol	18
STAR Biphasic Waveform	18
STAR Biphasic Energy Protocols for Powerheart AED	18
Operator Training Requirements	20

AED DESCRIPTION

The AED is a self-testing, battery-operated automated external defibrillator (AED). After applying the AED's defibrillation pads to the patient's chest, the AED automatically analyzes the patient's electrocardiogram (ECG) and advises the operator to push the button and deliver a shock if needed. The AED guides the operator through the rescue using a combination of voice prompts, audible alerts, and visible indicators. At the discretion of Advanced Life Support (ALS) personnel, the AED can be converted to manual override mode, and deliver a shock by pushing the SHOCK button. The AED can also provide non-diagnostic ECG monitoring.

INDICATIONS FOR USE

The AED with STAR Biphasic Waveform is intended to be used by personnel who have been trained in its operation. The operator should be qualified by training in basic life support, CPR/AED or other physician-authorized emergency medical response. The device is indicated for emergency treatment of victims exhibiting symptoms of sudden cardiac arrest who are unresponsive and not breathing. If the victim is breathing post-resuscitation, the AED should be left attached to allow for acquisition and detection of the ECG rhythm. If a shockable ventricular tachyarrhythmia recurs, the device will charge automatically and advise the operator to deliver therapy; or when in manual override mode, ALS personnel will monitor the ECG display and deliver a shock by pushing the shock button to deliver therapy.

When the patient is a child under 8 years of age or weighs less than 55 lbs (25kg), the AED should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. Therapy should not be delayed to determine the patient's exact age or weight.

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RHYTHMx® AED ECG ANALYSIS ALGORITHM

The RHYTHMx AED ECG analysis algorithm provides ECG detection capabilities, The features available with the AED include the following:

- Detection Rate
- Asystole Threshold
- Noise Detection
- Non-Committed Shock
- Synchronized Shock
- Pacemaker Pulse Rejection
- SVT Discriminators
- Supraventricular Tachycardia (SVT) Rate

DETECTION RATE

All ventricular fibrillation (VF) and ventricular tachycardia (VT) rhythms at or above this rate will be classified as shockable. All rhythms below this rate will be classified as non-shockable. This rate is programmable between 120 bpm (beats per minute) and 240 bpm via MDLink Software by the Medical Director. The default Detection Rate is 160 bpm.

ASYSTOLE THRESHOLD

The asystole baseline-to-peak threshold is set at 0.08 mV. ECG rhythms at or below 0.08 mV will be classified as asystole and will not be shockable.

NOISE DETECTION

The AED will detect noise artifact in the ECG. Noise could be introduced by excessive moving of the patient or electronic noise from external sources like cellular and radiotelephones. When noise is detected, the AED will issue the prompt *"ANALYSIS INTERRUPTED. STOP PATIENT MOTION"* to warn the operator. The AED will then proceed to reanalyze the rhythm and continue with the rescue.

NON-COMMITTED SHOCK

After the AED advises a shock, it continues to monitor the patient ECG rhythm. If the patient's rhythm changes to a non-shockable rhythm before the actual shock is delivered, the AED will advise that the rhythm has changed and issue the prompt *"RHYTHM CHANGED. SHOCK CANCELLED."* The AED will enter the CPR mode and prompt, "START CPR".

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SYNCHRONIZED SHOCK

The AED is designed to synchronize shock delivery on the R-wave. The AED will automatically attempt to synchronize to the R-wave. If delivery cannot be synchronized within one second, a non-synchronized shock will be delivered.

PACEMAKER PULSE DETECTION

The AED contains pacemaker pulse detection circuitry to detect pulses from an implanted pacemaker.

SVT DISCRIMINATORS

The AED is supplied with the SVT Discriminator enabled and with the default setting “NO THERAPY FOR SVT”. With the factory default setting of “NO THERAPY FOR SVT”, the AED will not shock an SVT rhythm.

SVT Discriminators are sophisticated filters that analyze the morphology of the ECG waveforms and distinguish VF/VT from SVT and Normal Sinus Rhythms (NSR). The SVT Discriminator will only be applied to rhythms that fall between the Detection Rate and the SVT Rate. The factory default setting for this feature is “NO THERAPY FOR SVT”, however the Medical Director can enable this feature using MDLink on the AED.

SVT RATE

All rhythms with rates between the Detection Rate and SVT Rate will be screened through a number of SVT Discriminators to classify them into VF/VT or SVT. Rhythms classified as SVT between the two set rates are not shockable. All SVT rhythms above the rates will be classified as shockable. The SVT Rate must be greater than the Detection Rate and is selectable between 160 and 300 bpm or, “NO THERAPY FOR SVT” can be selected via MDLink Software by the Medical Director on the AED.

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RESCUE PROTOCOL

The AED rescue protocol is consistent with the guidelines recommended by the American Heart Association (AHA)[1] and the International Liaison Committee on Resuscitation (ILCOR).

Upon detecting a shockable cardiac rhythm, the AED advises the operator to press the SHOCK button to deliver a shock and then advises the operator to start CPR.

Note: The standard CPR protocol of 120 seconds can be modified from 60 to 180 seconds in MDLink.

STAR BIPHASIC WAVEFORM

The STAR Biphasic Waveform is designed to measure the patient's impedance and deliver a customized shock. This allows the delivery of an optimized energy level to each patient. The energy levels for the AED are available in three different defibrillation shock[2] configurations. See table on next page and page 59 for additional information.

STAR BIPHASIC ENERGY PROTOCOLS FOR POWERHEART AED G3 PRO

Cardiac Science's patented STAR® Biphasic defibrillation waveform will deliver variable escalating energy that is customized to each patient's needs based upon a patient's thoracic impedance. This customization adjusts for the unique physical differences between patients. The range of impedance over which the device will deliver a shock is 25-180 Ohms. The AED comes equipped with five different FDA cleared biphasic energy protocols.

The operator, with guidance, direction and implementation from its designated AED program Medical Director, may select from one of these five protocols when placing the AED into service. The AED's factory default energy protocol is 200-300-300 Joule (J) escalating Variable Energy (VE). The first shock is delivered within the range of 140J-250J (200J nominal). Subsequent shocks are delivered within a range of 190J-360J (300J nominal). See next page.

[1] *"Guidelines 2005 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care" American Heart Association; Circulation Vol 112,Issue 24 Suppl. Dec 13, 2005*

[2] *The ultra-low current, low current and high current shocks are variable energy. The actual energy is determined by the patient's impedance.*

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These protocols are selected by using our MDLink software program. The five biphasic energy protocols available are as follows:

Energy Protocols	Shock Sequence[1]	Energy Level	Energy Range (J)
Factory Default	1.	200VE	140J-250J
	2.	300VE	190J-360J
	3.	300VE	190J-360J
Protocol #2	1.	200VE	140J-250J
	2.	200VE	140J-250J
	3.	300VE	190J-360J
Protocol #3	1.	150VE	105J-195J
	2.	200VE	140J-250J
	3.	200VE	140J-250J
Protocol #4	1.	150VE	105J-195J
	2.	150VE	105J-195J
	3.	200VE	140J-250J
Protocol #5	1.	200VE	140J-250J
	2.	200VE	140J-250J
	3.	200VE	140J-250J

[1] *The ultra-low current, low current and high current shocks are variable energy. The actual energy is determined by the patient's impedance.*

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OPERATOR TRAINING REQUIREMENTS

Persons authorized to operate the AED must have all of the following minimum training:

- Defibrillation training and other training as required by state, province, or country regulations.
- Training on operation and use of the AED.
- Additional training as required by the physician or Medical Director.
- A thorough understanding of the procedures in this manual.

Notes: Keep valid certificates of training and certification as required by state, province, or country regulations.

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SECTION 3 – GETTING STARTED

OVERVIEW

This section presents information on unpacking and setting up the AED

Topic	Page #
Unpacking and Inspecting	21
AED Parts	22
AED Modes	23
Powerheart AED G3 Pro Batteries	24
Rechargeable Battery and Charger	26
Defibrillation Pads (Electrodes)	28
AED Indicators	29
Setting the AED Internal Clock	33
Voice Prompts and Text Display	33

UNPACKING AND INSPECTING

Every attempt is made to ensure your order is accurate and complete. However, to be sure that your order is correct, verify the contents of the box against your packing slip.

If you have any questions about your order, contact Customer Service. See page 4.

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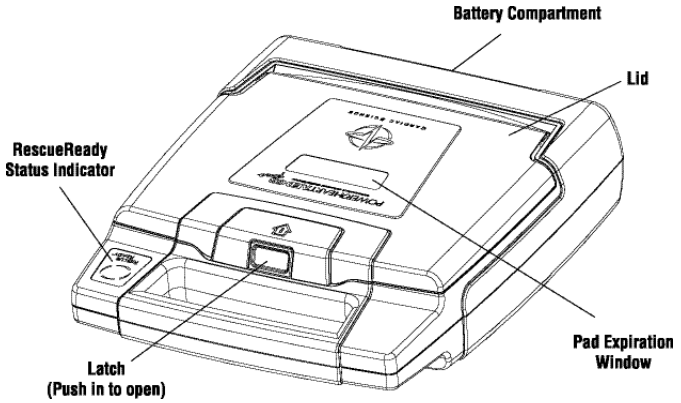
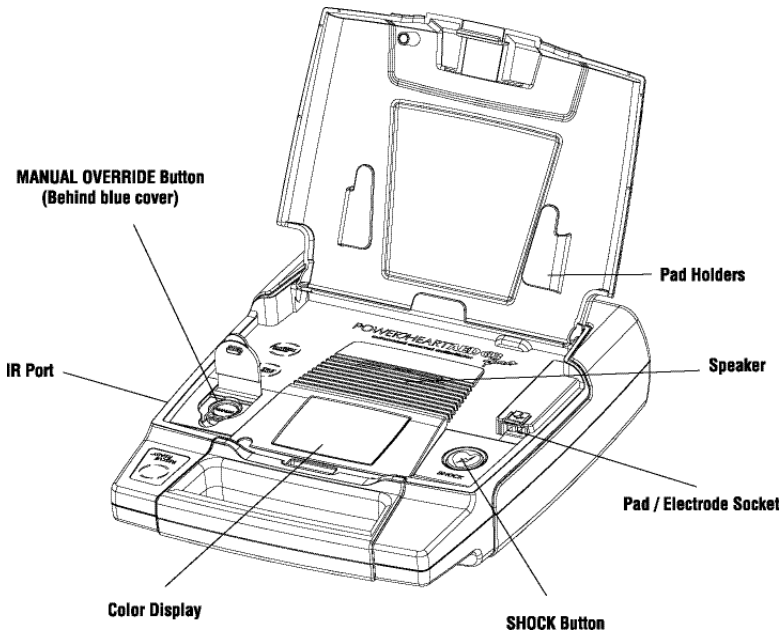
AED PARTS

The following drawings show the AED parts and their locations.





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AED MODES

Operating Mode: When the battery is installed and the lid is open. This is the mode the AED would be in during an actual rescue situation.

Standby Mode: When the battery is installed, but the lid is closed. This is the mode the AED is normally in when not being used in a rescue. The device will conduct its routine self-tests to ensure proper operation.

Storage Mode: When the battery is removed, such as during shipping or transport. With the battery removed, the AED is unable to perform self-tests or rescues.

ENVIRONMENTAL OPERATING AND STANDBY CONDITIONS

See Section 7 – Technical Data, Parameters, Environmental Operation and Standby Conditions.

⚠ ***CAUTION:*** Temperature Extremes
Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED; if the daily self-test determines environmental conditions outside of the AED's operating parameters, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Section 7 – Technical Data, Parameters, Operation and Standby Conditions.

SHIPPING AND TRANSPORT CONDITIONS

(For up to 1 week)
See Section 7 – Technical Data, Safety and Performance Standards/Shipping and Transportation Conditions.

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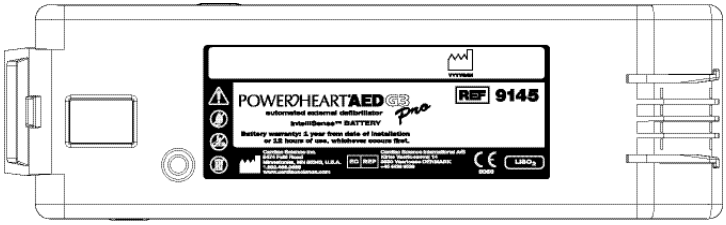
POWERHEART AED G3 PRO BATTERIES

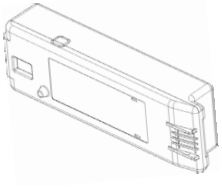
The 9300P is shipped with either an IntelliSense Battery (model 9145) or a rechargeable battery (model 9144).

Confirm which battery is included with the AED and see the applicable instructions below.

INTELLISENSE BATTERY™ (MODEL 9145)



The Cardiac Science IntelliSense battery technology offers you the most advanced battery capabilities available for defibrillators. Cardiac Science IntelliSense batteries contain an integrated memory chip that automatically stores important usage information, enabling the battery to maintain a complete history of its operating life. The actual battery history can be reviewed using the RescueLink software.
This history includes:



- Battery Identification
- Battery Type
- Original Date of Installation in an AED
- Number of Charges completed
- Time in Operation (hours:minutes)
- Days of Standby Operation
- Battery Capacity Remaining

BATTERY OPERATING LIFE

The battery operating life depends on the type of battery (9145 for Powerheart AED G3 Pro), actual usage and environmental factors.

The following table represents the expected life of the AED when used in Standby Mode.

Model	Estimated Shelf Life (from date of manufacture)	Warranty (from date of installation)	Typical Shocks
9145 Lithium Sulfur Dioxide	5 Years	1 Year or 12 hours of use, whichever occurs first	up to 290 Shocks

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BATTERY SHELF LIFE

The Cardiac Science AED IntelliSense batteries have a shelf life of five years. Shelf life is defined as the length of time a battery can be stored, prior to installation into AED, without degrading its performance.

Note: Storing the battery outside its specific range (0-50°C) will decrease battery life.

Note: Battery model 9145 is only for use with the Powerheart AED G3 Pro.

Note: Battery model 9142 and 9146 are only for use with the Powerheart AED G3. Battery model 9143 is only for use with the FirstSave AED G3.

WARNING: Battery (model 9145) is **NOT** Rechargeable
Do not attempt to recharge the battery. Any attempt to recharge the battery may result in an explosion or fire hazard. **Only battery (model 9144) is rechargeable.**

CAUTION: Lithium Sulfur Dioxide Battery
Pressurized contents: Never recharge, short circuit, puncture, deform, or expose to temperatures above 65°C (149°F). Remove the battery when discharged.

CAUTION: Battery Disposal
Recycle or dispose of the lithium battery in accordance with all federal, state and local laws. To avoid fire and explosion hazard, do not burn or incinerate the battery.

CAUTION: Use only Manufacturer Approved Equipment
Using batteries, defibrillation pads, cables, or optional equipment other than those approved by manufacturer may cause the AED to function improperly during a rescue.

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RECHARGEABLE BATTERY AND CHARGER

Either the non-rechargeable battery (model 9145) or the re-chargeable battery (model 9144) may come standard with the Powerheart AED Pro (model 9300P). The battery charger (model 9044) is sold separately. The rechargeable battery meets all respective IEC standards. All configurations comply with the system standard, IEC 60601-1-1.

DIRECTIONS FOR USE:

- The rechargeable battery is shipped half-charged. Charge battery fully before using.
- To charge, remove the rechargeable battery from the AED; the rechargeable battery can only be recharged when removed from the Powerheart AED G3 Pro.
- Plug the charger into an appropriate electrical outlet.
- Insert the charger cable into the rechargeable battery and ensure the yellow LED above the rechargeable battery symbol is on. **Charging is complete when the yellow Charge LED goes out, and the four green Fuel Gauge LEDs are continuously lit.**
- Remove the charger cable from the battery when done charging. Charging may be terminated early by removing the charger cable from the battery. If the battery is charged for a minimum of 3 hours, the stated capacities will be met.

Note: It is recommended that you keep a spare, non-rechargeable battery nearby. For longest battery life, when storing battery, discharge half-way. Do not store for extended periods at high temperature.

- The Powerheart AED G3 Pro will first indicate “Low Battery” while there is still sufficient charge remaining to perform at least one rescue. It is recommended to recharge the battery as soon as practical after the “Low Battery” indication. It is considered normal operation for the battery capacity gauge to show some remaining capacity when the “Low Battery” indication first occurs.

If the yellow Charge LED blinks continuously, a charging error has occurred. Contact the customer service in the event of a charging error.

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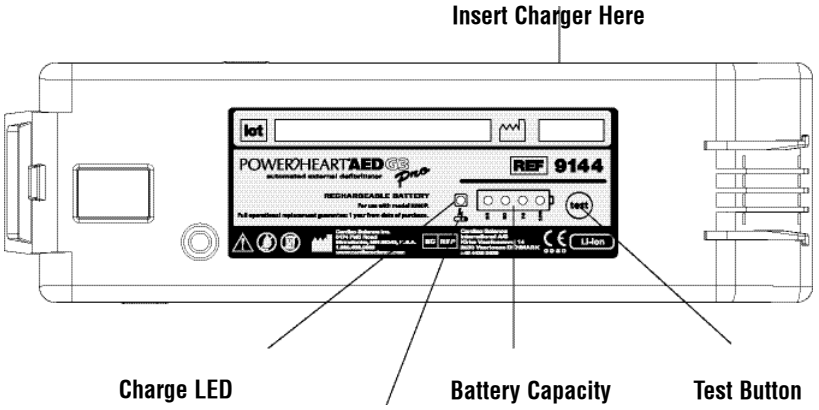
RECHARGEABLE BATTERY INDICATORS



SPECIFICATIONS

Battery Voltage:	11.1 V
Chemistry:	Lithium-ion. Refer to local regulations.
Compatibility:	Powerheart AED G3 Pro model 9300P
Battery Capacity:	60 shocks minimum (100 shocks typical) or 3 hours minimum of ECG display time (6 hours typical).
Battery Charge Time:	3 hours for stated capacity, 4.5 hours to fully charge completely depleted battery.
Battery Standby:	6 months
Battery Life:	2.5 years or 300 Battery charge-discharge cycles, whichever comes first.
Battery Weight:	1 lb. 3 oz

BATTERY INSTALLATION

1. With the label on the battery facing the AED battery compartment, insert the battery as shown in the drawing.

2. Push the latched end of the battery firmly into the AED, as shown in the drawing, until the battery snaps into place. With the battery correctly inserted, the AED should beep. The exposed side of the battery should be flush with the outside of the AED case.

3. Open the lid for 5 seconds to initiate a self-test. If the battery and electrodes are installed properly, **STATUS INDICATOR** will turn **GREEN**. Close the lid.

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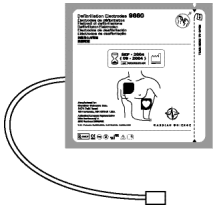
DEFIBRILLATION PADS (ELECTRODES)



The defibrillation pads come in a ready-to-use, sealed package containing one pair of self-adhesive pads with an attached cable and connector. The pads are disposable and should be discarded after each rescue.

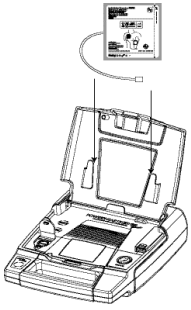
The pads have a limited shelf life and should not be used beyond the expiration date. Keep a fresh, unopened pair of pads plugged into the AED at all times. Refer to the pad package label for operation temperatures.

An audible and visual alert will indicate after the self-test if the electrodes are missing, unplugged or damaged.

⚠ ***CAUTION:*** Possible Improper AED Performance

Using defibrillation pads that are damaged or expired may result in improper AED performance.

PAD INSTALLATION



1. Open the lid of the AED.
2. Place the pad package into the lid so that the expiration label is visible through the clear window on the lid. The expiration date of the electrodes will then be readable without opening the lid of the AED.
3. Match the color of the connectors (red to red), then slightly lift the tab of the pad socket and plug the pad connector into the pad socket.
4. Tuck the excess cable length in the bottom holder as shown in the drawing. With the pad package completely secured to the AED lid, close the lid.
5. Make sure the expiration date is visible through the clear window of the lid. Check to make sure that the **STATUS INDICATOR** is **GREEN**.

⚠ ***CAUTION:*** Use only Cardiac Science Approved Equipment
Using batteries, defibrillation pads, cables, or optional equipment other than those approved by Cardiac Science may cause the AED to function improperly during a rescue.

⚠ ***CAUTION:*** Possible Improper AED Performance
Using defibrillation pads that are damaged or expired may result in improper AED performance.

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DIRECTIONS FOR USE:

1. Do NOT open until ready to use, short term use only.
2. Ensure the skin site is clean and dry.
3. Separate one pad from liner.
4. Place one pad on skin on indicated location.
5. Peel and place remaining pad.

AED INDICATORS

The following indicators are located on the AED.

The **STATUS INDICATOR** is located on the AED handle. When this indicator is **GREEN**, the AED is RescueReady. This means the AED self-tests have verified the following:

- Battery has an adequate charge.
- Pads are properly connected to the AED and in working order.
- Integrity of the internal circuitry is good.

When the **STATUS INDICATOR** is **RED**, maintenance is required.

AUDIBLE MAINTENANCE INDICATOR

When the daily, weekly or monthly self-test determines service is required, an audible beep is sounded every 30 seconds until the lid is opened or the battery power is depleted. Opening and closing the lid may deactivate the beep. If the error is not corrected by the next automatic self-test, the beep will be reactivated.

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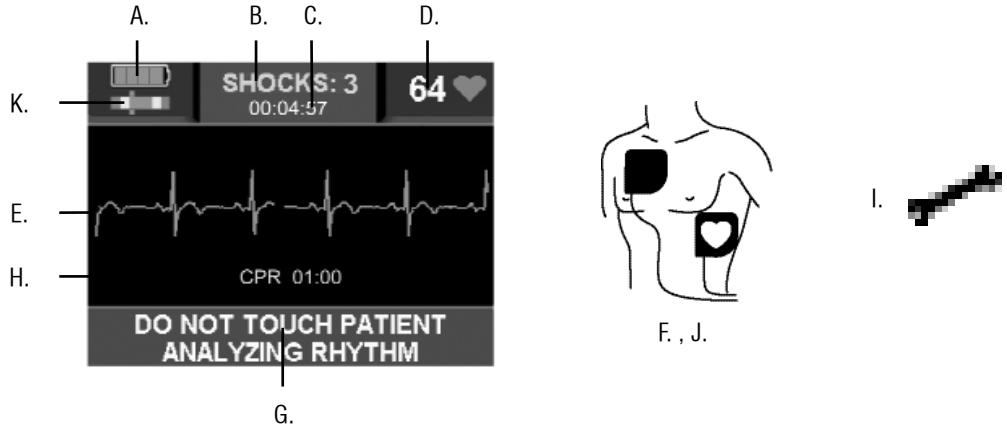
DIAGNOSTIC PANEL



ECG DISPLAY SPECIFICATIONS:

Data Display:	5 seconds 8.9 cm (3.5”) diagonal transreflective TFT display, 320x240 pixels, quarter VGA
Resolution:	4.47 dots/mm (113.5 dots/in.)
Sweep speed:	1.39 cm/s
ECG bandwidth:	3-32 Hz

A. **SMARTGAUGE BATTERY** Indicator
This indicator displays the battery capacity. At maximum charge, the battery is GREEN. With use, the GREEN level will gradually go out from right to left as the battery capacity decreases. Once the battery level is depleted, the battery indicator will turn to RED, and the battery should be replaced.

Note: When the battery indicator is initially RED – upon lid opening or at any time during a rescue – a “BATTERY LOW” prompt will be issued at once. However, the AED is capable of delivering at least nine more defibrillation shocks after the first time a “BATTERY LOW” prompt is issued.

B. **NUMBER OF SHOCKS DELIVERED** Indicator
This indicator counts and displays the number of shocks delivered.

C. **ELAPSED RESCUE TIME** Indicator
This indicator times and displays the elapsed rescue time.

Note: There is a 3 second delay between the time the AED lid is opened and the start of the rescue (when the lid was first opened).

D. **HEART RATE** Indicator
This indicator displays the patient’s heart rate.

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E. **ECG** Display
Four and a half seconds of the patient's ECG is displayed.

F. **PAD PLACEMENT** Display
Visually assists the rescuer with pad placement with the directions for use. Appropriate text prompts are also displayed.

G. **TEXT** Display
The text display has 2 lines of text. It provides the operator with information regarding system initialization, text version of the voice prompts and data during a rescue, and diagnostics.

System initialization occurs when the lid is first opened. The text display shows the operator the identifiers for the internal code, voice prompts and text prompts versions.

H. **CPR** Counter
During CPR, a countdown timer will be displayed.

I. **SERVICE** Indicator
When apparent, indicates that service is required that can only be performed by qualified service personnel.

J. **PAD** Indicator
When flashing with voice and text prompt indicating "Check Pads", indicates to check pads when pads are:
- Not properly connected to the AED
- Not within operational specifications (cold, dried, damaged)
- Disconnected from the patient during a rescue

K. **Z-BAR** Indicator
The Z-Bar provides a relative visual graphical indicator of the total transthoracic impedance between the two defibrillation pads. The Z-Bar is used in the assessment of:
- Adequate pad placement
- Pad quality and integrity
- Pad adhesion to the patient's skin
- Proper pad connection to the AED
- Provides for quick assessment between pads off and pads shorted

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CONTROL BUTTONS

The AED has two buttons.

SHOCK BUTTON

The SHOCK button is located at the far right of the control panel.

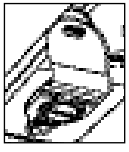
SHOCK INDICATOR

Delivers a defibrillation shock. The word SHOCK and the shock button indicator LED will illuminate RED when the AED is ready to deliver a defibrillation shock to the patient. Note modification to behavior below when in manual mode.

MANUAL OVERRIDE BUTTON

The MANUAL OVERRIDE button is located at the far left of the control panel and converts the device from automated mode to manual. This feature should only be used by ALS personnel. The factory default setting for Manual Override functionality is enabled, however the Medical Director can disable/enable this feature via MDLink.

MANUAL OVERRIDE



- Lift the cover to access the button.
- Converts to manual standby mode when pushed once, a voice prompt *"Press Manual Button Again to Confirm"*, will be heard. Converts to manual mode when MANUAL button is pressed again.
- If the rescuer does not confirm within 30 seconds of the capacitors charging, the AED will revert back to AED Mode.
- If the Medical Director has disabled this feature in MDLink, an icon indicating No MANUAL MODE will appear in the bottom left of the display.

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SETTING THE AED INTERNAL CLOCK

The internal clock is preset at Central Standard Time and should be reset to the correct date and local time. The AED will automatically adjust itself for daylight savings time. This feature can be turned off using the MDLink software. To set the clock, you will need a PC with Windows 95 or later operating system, RescueLink software installed, an IR port on the PC, and an IR cable as specified below.

To set the clock settings:

- Open the lid and remove pads from the pads socket.
- Ensure that the PC is set at the correct local time and date.
- Point IR port on the AED to IR eye on the PC and select G3 Pro.
- Run the RescueLink software on the PC.
- Verify that the voice prompt states *"Communications Mode".*
- Click **COMMUNICATIONS** on the main menu. Select **AED DATE AND TIME**.
- Click on the **GET** button to review the current time in the AED.
- If the time and date is incorrect, click **SET** to set new time and date. The AED date and time will automatically be updated to the PC's time and date.
- Reinstall pads per instructions on page 28.
- Close the lid.

Note: The IR port on the AED is designed to work with IR cable ACT-IR220LN115 from ACTiSys Corp. on Windows based PCs only. Please contact customer service to order, P/N 162-0108-001. Other IR products may interfere with the transmission and are not for use with the AED.

VOICE PROMPTS AND TEXT DISPLAY

The voice prompts activate when the AED lid is opened and help guide the operator through the rescue. The text display provides a visual display of most of the audible voice prompts.

The following table lists the voice and text prompts and a description of when the prompts are issued.

STANDARD PROMPTS

VOICE PROMPT	TEXT DISPLAY	SITUATION
"Tear Open Package and Remove Pads."	*TEAR OPEN PACKAGE REMOVE PADS*	When the lid is opened, this phrase is repeated twice to initiate the rescue sequence.
"Peel One Pad from Plastic Liner."	*PEEL ONE PAD FROM PLASTIC LINER*	Repeats until one pad is peeled off of the liner.
"Place One Pad on Bare Upper Chest."	*PLACE ONE PAD ON BARE UPPER CHEST*	Repeats twice while one pad is placed.
"Peel Second Pad and Place on Bare Lower Chest as Shown."	*PEEL SECOND PAD PLACE ON LOWER CHEST*	Repeats until both pads are placed on the patient.

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VOICE PROMPT	TEXT DISPLAY	SITUATION
"Press Pads Firmly to Patient's Bare Skin."	*PRESS PADS TO PATIENT'S BARE SKIN*	When better connectivity is required because impedance is too high.
"Do Not Touch Patient! Analyzing Rhythm."	*DO NOT TOUCH PATIENT ANALYZING RHYTHM*	When the AED is analyzing the cardiac rhythm of the patient.
"Shock Advised."	*SHOCK ADVISED*	When the AED is preparing to deliver a defibrillation shock.
"Charging."	*CHARGING*	Repeats while AED is charging.
"Stand Clear! Push Flashing Button to Deliver Shock."	*STAND CLEAR PUSH BUTTON TO SHOCK*	After the AED is fully charged and ready to deliver the defibrillation shock. The RED **SHOCK** indicator flashes and the phrase repeats for 30 seconds or until the **SHOCK** button is pushed.
"Plug in Pads Connector"	*PLUG IN PADS CONNECTOR*	When the pad socket does not have defibrillation pads or ECG electrodes connected.
"Shock Delivered"	*SHOCK DELIVERED*	After the AED delivers a defibrillation shock
"It is now safe to touch the patient."	*IT IS NOW SAFE TO TOUCH THE PATIENT*	Advises the rescuer when it is safe to touch the patient.
Start CPR	*START CPR*	After the AED delivers a defibrillation shock. After the AED detechs a non-shockable rhythm.
Give 30 compressions Then Give Two Breaths	*30 COMPRESSIONS 2 BREATHS*	Perform CPR for 2 minutes
"Check Pads"	*CHECK PADS*	Occurs when patient impedance is too low or the pads are shorted.
"Battery Low"	*BATTERY LOW*	Occurs once when the battery voltage becomes low, although a rescue can continue for approximately 9 more shocks. When the battery is too low to perform a rescue, the device halts operation and displays "Battery Low" on the Display, the NVI will turn to RED and the Sonalert will beep. No voice prompt is issued. If completely depleted, all AED activity will terminate.
"Analysis Interrupted. Stop Patient Motion."	*ANALYSIS INTERRUPTED STOP PATIENT MOTION*	When the AED detects ECG noise artifact, stop moving or touching the patient.
"Open Lid to Continue Rescue"	*OPEN LID TO CONTINUE RESCUE*	When the lid is inadvertently closed during a rescue, this prompt will repeat for 15 seconds.
"Rhythm Changed. Shock Cancelled."	*RHYTHM CHANGED SHOCK CANCELLED*	When the device is prepared to shock then detects a change in rhythm and therefore cancels the shock.

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VOICE PROMPT	TEXT DISPLAY	SITUATION
"ECG Monitoring Mode"	*ECG MONITORING MODE*	When ECG Patient Cable is inserted into the pad socket. When the Manual Mode button is pressed when in ECG Monitoring Mode.
"Communications Mode"	*COMMUNICATIONS MODE*	When the lid is open and IR is transmitting the AED.
(Beep)	*N/A*	One "Beep" occurs in 30-second intervals during CPR when enabled by the MDLink software program, "Beep" occurs when the AED requires maintenance.
"Continue CPR"	*CONTINUE CPR*	During CPR mode when enabled, or when a rescue is resumed in CPR mode after being interrupted by the lid closing.
"Service Required"	*SERVICE REQUIRED*	Occurs after the self-tests determine that the AED is not functioning properly. The prompt *"SERVICE REQUIRED"* will be heard when the lid is opened. The red **SERVICE** indicator will illuminate and *"SERVICE REQUIRED"* will repeat until you close the lid. After closing the lid, an alarm beep will be heard until the battery is removed or becomes completely depleted.

ADVANCED FEATURE PROMPTS

VOICE PROMPT	TEXT DISPLAY	SITUATION
"Entering Manual Mode. Press Button Again to Confirm"	*MANUAL MODE PRESS BUTTON TO CONFIRM*	After ALS presses the MANUAL button once to initiate the manual mode.
"Manual Mode. Charging"	*MANUAL MODE CHARGING*	After ALS presses the MANUAL button again to confirm.
"Manual Mode Not Confirmed."	*MANUAL MODE NOT CONFIRMED*	When the MANUAL button is not pressed a second time within five seconds, the device stays in AED mode.
"If Shockable Rhythm, Press SHOCK Button to Deliver Therapy."	*IF SHOCKABLE RHYTHM PRESS SHOCK BUTTON*	When in manual mode, prompts ALS personnel to press SHOCK button if ECG indicates a shockable rhythm.
"Shockable Rhythm. Attach Defibrillation Pads."	*SHOCKABLE RHYTHM ATTACH DEFIBRILLATION PADS*	When the device is performing ongoing ECG monitoring via the ECG Patient Cable Kit and detects a shockable rhythm.
"Device Will Disarm in :30"	*DEVICE WILL DISARM IN :30*	Should the rescuer go into manual mode and decide that AED mode is more appropriate, the AED will revert back to AED mode 30 seconds after charging is complete. The seconds will count down from 30 on the display.

When "Remain in manual mode" has been enabled (Using MDLink software). The AED will disarm but remain in Manual Mode. See page 41.

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SECTION 4 – INSTRUCTIONS FOR USE

OVERVIEW

This section presents information about how to use the AED to perform a rescue.

Topic	Page #
Operating Modes	37
Step 1: Assessment and Pad Placement	38
Step 2: ECG Analysis (AED Mode)	39
Step 3: Shock Delivery and CPR Mode (AED Mode)	40
Step 4: Post Rescue	40
Using Manual Override (Manual Mode)	41
ECG Display for Ongoing Monitoring	42
Z-BAR Indicator	43
Warnings	44

OPERATING MODES

The AED comes in three operating models. The AED is pre-set to AED mode, but the user can change the mode during each unique rescue. The energy delivered is determined by the Medical Director and programmed into the AED prior to the rescue.

AED MODE (DEFAULT)

For patients exhibiting signs of sudden cardiac arrest. Once defibrillation pads are placed on the patient, the AED analyzes the heart rhythm. If a shockable rhythm is detected, the AED automatically charges to a pre-set energy level and prompts rescuer to push the **SHOCK** button to deliver therapy.

MANUAL MODE

For patients exhibiting signs of sudden cardiac arrest. Once the defibrillation pads are placed on the patient, a trained ALS rescuer may wish to read the ECG display to determine whether or not a shock is required. This mode is activated by pushing the manual button once then again to confirm; the device will begin charging. If the rescuer deems that the rhythm is shockable, therapy can be delivered by pressing the **SHOCK** button. The algorithm will search for the R-wave for up to one second; if an R-wave cannot be deleted in that time, an asynchronous shock will be delivered. Then, the AED will revert back to CPR mode. By entering manual mode, the rescuer is taking responsibility to identify a shockable rhythm and to administer a shock. Should the rescuer go into manual mode and decide that AED mode is more appropriate, the AED will revert back to AED mode 30 seconds after charging is complete. The seconds will count down on the display. If the Medical Director has disabled this feature in MDLink, an icon indicating NO MANUAL MODE will appear in the bottom left of the display. With Manual Mode enabled and the Medical Director has also enabled "REMAIN IN MANUAL MODE" the AED will not revert to the AED or CPR mode, but will remain in Manual mode.

ECG MONITORING MODE

For patients who are conscious and breathing and require basic ECG monitoring. Non-diagnostic ECG patient monitoring can be activated by inserting the ECG patient monitoring cable into the electrode socket on the AED, connecting the 3-lead patient cables to the specialized ECG electrodes and placing as directed onto the patient. Should the AED detect a shockable rhythm, defibrillation pads should be placed on the patient, the ECG patient monitoring cable removed from the electrode socket on the AED and the connector should be plugged into the pad socket to enable a defibrillation shock.

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STEP 1: ASSESSMENT AND PAD PLACEMENT

PREPARATION

Determine that the patient is over 8 years of age or weighs more than 55 pounds (25 kg) and exhibits the following:

The patient is unresponsive, and
The patient is not breathing.

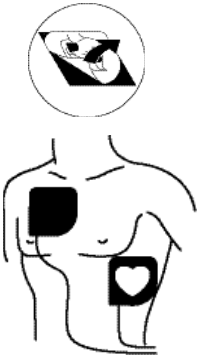
Remove clothing from the patient's chest. Ensure the skin site is clean and dry. Dry the patient's chest and shave excessive hair if necessary.

Open the AED lid and follow prompts.

Note: When the patient is a child under 8 years of age or weighs less than 55 lbs (25kg), the AED should be used with the Model 9730 Pediatric Attenuated Defibrillation Electrodes. Therapy should not be delayed to determine the patient's exact age or weight. See the directions for use accompanying pediatric electrodes for procedure on changing adult electrodes to pediatric.

PLACE PADS

The AED will issue the prompt *"Tear Open Package and Remove Pads."* Keep the pads connected to the AED, tear the package along the dotted line and remove the pads from the package. Leave the package attached to the pad wires.



After the prompt *"Peel One Pad From Plastic Liner,"* with a firm, steady pull, carefully peel one pad away from the release liner.

Then, after the prompt *"Place One Pad on Bare Upper Chest,"* place the pad with the sticky side on the patient's skin on the upper right chest, placing the top of the pad on the collarbone. Avoid placing the pad directly over the sternum.

Finally, after the prompt *"Peel Second Pad and Place on Bare Lower Chest As Shown,"* pull the second pad from the release liner and place it on the lower left chest, below and left of the breast.

Note: The AED is compatible with Cardiac Science polarized pacing (P/N 9660), non-polarized (P/N 9131), pediatric (P/N 9730), and monitoring electrodes (for use with ECG Monitoring Kit (P/N 5111). When using polarized pacing or monitoring electrodes, refer to the placement indicated on their respective packages. Non-polarized electrodes and pediatric electrodes can be placed in either position as shown on the pad package.

Note: When using polarized pacing pads (P/N 9660) see the diagram on the pads for specific placement of each pad.

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When the pads are placed, the voice prompt will say *"Do Not Touch Patient. Analyzing Rhythm."* If the pads are not properly placed or become disconnected at any time during the rescue, the voice prompt *"Check Pads"* will be heard. When this occurs, ensure that:

Pads are firmly placed on clean, dry skin
Pads cable is securely plugged into the AED

STEP 2: ECG ANALYSIS (AED MODE)

As soon as the AED detects proper pad placement, the voice prompt *"Do Not Touch Patient. Analyzing Rhythm."* will be heard. The AED will begin to analyze the cardiac rhythm of the patient.

If a shock is advised, the voice prompt will say, *"Shock Advised. Charging."* When the AED is ready to deliver a defibrillation shock, the **SHOCK** button will flash and the prompt, *"Stand Clear. Push Flashing Button to Deliver Shock"* will be heard. The tone, flashing button, and voice prompt will continue until the shock is delivered or change in rhythm is detected, or 30 seconds elapse.

When the AED is charged, it continues to analyze the patient's heart rhythm. If the rhythm changes and a shock is no longer needed, the AED will issue the prompt *"Rhythm Changed. Shock Cancelled,"* disarm and enter CPR mode.

If noise is detected during analysis, the AED will warn you with the prompt *"Analysis Interrupted. Stop Patient Motion"* and restart the analysis. This usually occurs if the patient is excessively jostled or there is a strong electromagnetic emitting electronic device nearby (within 2 meters). Remove the electronic device or stop the excessive motion when you hear this prompt.

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STEP 3: SHOCK DELIVERY AND CPR MODE (AED MODE)

For information on the Manual Mode or ECG Monitoring mode, see pages 41-42.

When the AED is ready to deliver a defibrillation shock, the **SHOCK** button will flash and the prompt *"Stand Clear. Push Flashing Button to Deliver Shock"* will be heard.

Make sure no one is touching the patient and push the **SHOCK** button to deliver a defibrillation shock. If you do not push the **SHOCK** button within 30 seconds of hearing the prompt, the AED will disarm and enter CPR mode.

After the AED delivers a defibrillation shock, the voice prompt will say "Shock Delivered." The AED will then prompt you to start CPR.

Note: During a rescue, the screen displays voice prompts, elapsed time of rescue and number of shocks delivered.

CPR MODE

After shock delivery or detection of a non-shockable rhythm, the AED automatically enters CPR mode. The voice prompt will say, "It is now safe to touch the patient. Start CPR."

During the CPR time-out period, the AED will not interrupt the CPR mode. After the CPR time-out period has expired, the voice prompt "Do Not Touch Patient. Analyzing Rhythm."will be heard.

Note: During CPR mode, a countdown timer is displayed.

If the patient is conscious and breathing normally, leave the pads on the patient's chest connected to the AED. Make the patient as comfortable as possible and wait for Advanced Life Support [ALS] personnel to arrive. Continue to follow the voice prompts until the ALS personnel arrive, or proceed as recommended by the Medical Director.

STEP 4: POST RESCUE

After transferring the patient to ALS personnel, prepare the AED for the next rescue:

1. Retrieve the rescue data stored in the internal memory of the AED by using RescueLink software installed on a PC (see detailed procedure in the Data Management section).
2. Connect a new pair of pads to the AED.
3. Close the lid.
4. Verify that the **STATUS INDICATOR** on the AED handle is **GREEN**.

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USING MANUAL OVERRIDE (MANUAL MODE)

For use by qualified ALS personnel only. The AED has a manual override feature which overrides the AED's automatic analysis protocol. By entering this mode, the rescuer is taking responsibility to identify a shockable rhythm and to administer a shock. The default setting for the manual override is "enabled". When enabled, the Manual Override option allows the user to charge the AED and deliver a shock at the user's discretion. After the shock button is pushed or 30 seconds has elapsed, the device will automatically exit the manual mode and return to the AED mode.

Optionally, the manual override default behavior may be modified so that after entering manual mode, the AED will remain in the manual override mode for the duration of the rescue. This feature is enabled by selecting the "REMAIN IN MANUAL MODE" option in the MDLink software and can be configured during the initial set up of the AED.

STEP 1: Please refer to: "STEP 1: ASSESSMENT AND PAD PLACEMENT" on page 38.

STEP 2: Lift blue plastic cover on far left of diagnostic panel.

STEP 3: Push the MANUAL button once to initiate. The voice prompt and corresponding text prompts will indicate *"Entering manual mode. Press button again to confirm."*

STEP 4: The MANUAL button must be pushed again to confirm and convert to manual mode. The manual indicator on the display panel will be active. The voice and corresponding text prompts will indicate, *"Manual Mode."*

Note: The MANUAL MODE is initially displayed on the screen when activated. If the Medical Director has disabled this feature in MDLink, an icon indicating NO MANUAL MODE will appear in the bottom left of the display. Continue the rescue in AED Mode.

STEP 5: The voice prompts and corresponding text prompts will indicate, *"If rhythm is shockable, press SHOCK button to deliver therapy"*. Read the ECG and determine if the rhythm is shockable. If so, press the **SHOCK** button to deliver therapy.

Note: The RHYTHMx analysis algorithm is disabled in manual mode. It is the rescuer's responsibility to determine if a shock is necessary.

STEP 6: After the shock button has been pressed or 30 seconds elapses without the shock button being pressed, the AED will revert to AED MODE and prompt, "START CPR". Follow the voice prompts. If "Remain in Manual Mode" has been enabled, the device will remain in Manual Mode.

STEP 7: To re-enter manual mode, press the MANUAL button ONCE.

Note: Should the rescuer go into manual mode and decide that AED mode is more appropriate, the AED will revert back to AED mode 30 seconds after charging is complete. The seconds will count down on the display. If "Remain in Manual Mode" has been enabled, the device will remain in Manual Mode.

EXITING MANUAL MODE

Default: The device will return to AED mode after:

- Pushing the shock button
- 30 seconds has elapsed without pushing the shock button
- Closing the AED lid momentarily
- Removing the battery momentarily
- Attaching the optional 3-lead ECG monitoring cable
- Disconnecting the pads from the AED
- Removing the pads from the patient

EXITING MANUAL MODE WHEN "REMAIN IN MANUAL MODE" HAS BEEN ENABLED

- Closing the AED lid momentarily
- Removing the battery momentarily
- Attaching the optional 3-lead ECG monitoring cable (upon reattaching the defibrillation pads the AED will be in manual mode).

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ECG DISPLAY FOR ONGOING MONITORING (ECG MONITORING MODE)

At the discretion ALS personnel, the AED can be used for ongoing ECG patient monitoring. By using a separately sold ECG Patient Monitoring Kit (PN: 5111), the AED provides non-diagnostic ECG display of the patient's heart rhythm for attended patient monitoring. It is not necessary to turn the device off prior to connecting the ECG cable. While connected to the AED, the shock capability is disabled.

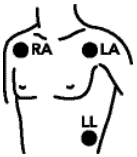
Indications for use:
A conscious or breathing patient, regardless of age.

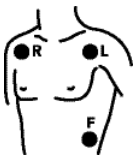
Contraindications:
No known contraindications.

The separately sold ECG Patient Monitoring Kit is designed for connection to ECG electrodes per AAMI or IEC color convention and is required to use this feature. Once connected the AED displays and evaluates the patient's ECG (Lead II). Follow all prompts from the AED.

The kit includes a cable which contains electronics (with a non-replaceable battery) that is inserted into the electrode socket on the AED; the other end of the cable has three patient leadwires. Each leadwire terminates in an ECG electrode connector to attach to a disposable ECG electrode.

ELECTRODE INSTALLATION





1. Remove packaging from kit components. Connect the ECG electrodes to the colored leadwires.

2. Peel off the adhesive backing from the ECG electrodes. Apply the ECG electrodes to the patient's bare chest accordingly:
   - RA/R Electrode – Place near the right midclavicular line, directly below the clavicle.
   - LA/L Electrode – Place near the left midclavicular line, directly below the clavicle.
   - LL/F Electrode – Place between the 6th and 7th intercostals space on the left midclavicular line.

Note: Make sure there is adequate space between the defibrillation electrodes of at least 1 inch or 2.54 cm (if previously applied) and the ECG monitoring electrodes.

3. Plug the ECG patient cable into the electrode socket located on the AED.

Once connected the AED displays and evaluates the patients ECG (Lead II) and heart rate. Follow all prompts from the AED. Check the patient if:

- Indicated by the observed ECG or heart rate display.
- The patient becomes unresponsive or stops breathing.
- The AED prompts *"Shockable Rhythm. Attach Defibrillation Pads".*

If appropriate, disconnect the ECG patient cable from the AED and connect the defibrillation pads to pads socket. Then, place the defibrillation pads on the patient as shown. NOTE: Make sure there is adequate space between the defibrillation pads of at least 1 inch or 2.54 cm and the ECG monitoring electrodes.

Note: If the Manual Mode button is pressed when in ECG Monitoring Mode, a voice prompt will indicate *"ECG Monitoring Mode"*.

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Z-BAR™ INDICATOR

The Z-Bar provides a relative visual graphical indicator of the total transthoracic impedance between the two defibrilation pads. The Z-Bar is used in the assessment of:

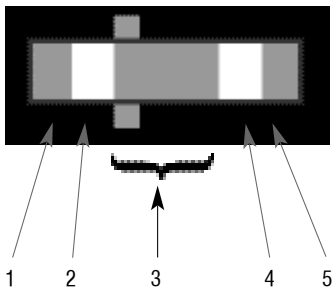
- Adequate Pad placement
- Pad quality and integrity
- Pad adhesion to the patient's skin
- Proper Pad connection to the AED
- Provides for quick assessment between PADS OFF and PADS SHORTED

Note: The Z-Bar is displayed on all therapy screens with the exception of the ECG MONITORING screen. On the ECG MONITORING screen the Z-Bar will be displayed only if the detection lead is set to Pads.

The Z-Bar is divided into 5 sections. The ideal operating range is section 3 (impedance range from 30 to <150).

Z-BAR

SECTION	MEASURED IMPEDANCE RANGE (OHMS)	DESCRIPTION	COLOR FILL
1	<20	Lower Limit Alarm – Non operational range	Red
2	>20 but < 30	Lower marginal operating range. Indicates potential Pad degradation in Pad quality or position	Yellow
3	**>30 but < 150**	**Normal operating range**	**Green**
4	>150 but <180	Upper marginal operating range. Indicates potential Pad degradation in Pad quality or position	Yellow
5	>180	Upper Limit Alarm – Non operational range	Red



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WARNINGS

The following cautions must be observed to prevent problems during the rescue.

DANGER: Fire and Explosion Hazard
Exercise caution when operating the AED close to flammable gases (including concentrated oxygen) to avoid possible explosion or fire hazard.

WARNING: Shock Hazard
Defibrillation shock current flowing through unwanted pathways is potentially a serious electrical shock hazard. To avoid this hazard during defibrillation abide by all of the following:

- Do not touch the patient, unless performance of CPR is indicated
- Do not touch metal objects in contact with the patient
- Keep defibrillation pads clear of other electrodes or metal parts in contact with patient
- Disconnect all non-defibrillator proof equipment from the patient before defibrillation

WARNING: Shock and Possible Equipment Damage
Disconnect all non-defibrillator proof equipment from the patient before defibrillation to prevent electrical shock and potential damage to the equipment.

CAUTION: Use only Approved Equipment
The Rechargeable battery is made solely for Powerheart AED G3 Pro, and is NOT to be used with any other AED models. Using batteries, pads, cables, or optional equipment other than those approved by the manufacturer may cause the AED to function improperly during a rescue.

CAUTION: Possible Improper AED Performance
Using defibrillation pads that are damaged or expired may result in improper AED performance.

CAUTION: Possible Radio Frequency (RF) Susceptibility
RF susceptibility from cellular phones, CB radios and FM 2-way radio may cause incorrect rhythm recognition and subsequent shock advisory. When attempting a rescue using the AED, do not operate wireless radiotelephones within 2 meters of the AED – turn power OFF to the radiotelephone and other like equipment near the incident.

CAUTION: Possible Interference with Implanted Pacemaker
Therapy should not be delayed for patients with implanted pacemakers and a defibrillation attempt should be made if the patient is unconscious and not breathing. The AED has pacemaker detection and rejection, however with some pacemakers the AED may not advise a defibrillation shock[1].

Placing Defibrillation Pads:

- Do not place the defibrillation pads directly over an implanted device.
- Place the defibrillation pads at least one inch from any implanted device.

CAUTION: Moving the Patient During a Rescue
During a rescue attempt, excessive jostling or moving of the patient may cause AEDs to improperly analyze the patient's cardiac rhythm. Stop all motion or vibration before attempting a rescue.

[1] *Cummins, R., ed., Advanced Cardiac Life Support; AHA (1994): Ch. 4.*

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SECTION 5 – DATA MANAGEMENT

OVERVIEW

The AED is designed for ease of data management and review. The data stored in internal memory can be viewed on the PC display using the RescueLink software.

Topic	Page #
Recording Rescue Data	45
Reviewing Rescue Data	45
Multiple Rescue Functionality	46

RECORDING RESCUE DATA

RECORDING DATA IN INTERNAL MEMORY

The AED automatically stores up to 60 minutes of rescue data.

REVIEWING RESCUE DATA

RETRIEVING DATA FROM MEMORY

1. Open the RescueLink software program on the PC.
2. Open the AED lid.
3. Point IR port on the AED to IR cable attached to the PC.
4. Select COMMUNICATIONS, GET RESCUE DATA on the RescueLink software program.
5. Select INTERNAL MEMORY OF AED then select OK.
6. The voice prompt will say “COMMUNICATIONS MODE”.
7. Select a rescue to download by highlighting the date and press OK.
8. Wait for the date to appear in RescueLink.
9. Close the lid.

Note: The approved IR cable is ACT-IR220LN115 from ACTiSYS Corp. Please contact customer service to order, P/N 162-0108-001.

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MULTIPLE RESCUE FUNCTIONALITY

The AED can store up to 60 minutes of ECG monitoring time in the AED's internal memory. Multiple rescues can be stored in the internal memory, allowing the rescuer to administer additional rescues without downloading the data to a PC. Should the internal memory become full, the AED will purge rescues as needed, beginning with the oldest rescue.

When downloading data, RescueLink will enable the user to select which rescue to download. See the RescueLink application HELP files for more information.

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SECTION 6 – MAINTENANCE & TROUBLESHOOTING

OVERVIEW

This section presents information about the AED diagnostics self-tests, maintenance, and service indications.

Topic	Page #
Self-Tests	47
Indicator Troubleshooting Table	48
Scheduled Maintenance	49
Authorized Repair Service	50
Frequently Asked Questions	51

SELF-TESTS

The AED has a comprehensive self-test system that automatically tests the electronics, battery, pads, and high voltage circuitry. Self-tests are also activated every time you open and close the AED lid.

When performing the self-tests, the AED completes the following steps automatically.

- Turns itself ON, and the **STATUS INDICATOR** changes to **RED**.
- Performs the self-test.
- If successful, the **STATUS INDICATOR** reverts to **GREEN**.
- Turns itself OFF if the lid is closed.

There are three types of automatic self-tests. The Daily Self-Test checks the battery, pads, and the electronic components. The Weekly Self-Test completes a partial charge of the high voltage electronics current in addition to the items tested in the Daily Self-Test. During the Monthly Self-Test, the high voltage electronics are charged to full energy, in addition to the Daily Self-Test items.

Self-tests will be initiated upon opening the lid and again upon closing the lid. If the self-test detects an error, the **STATUS INDICATOR** will remain **RED**. Upon closing the lid, an audible alert will be issued. The display will indicate the source of the problem according to the Indicator Troubleshooting Guide Table on the next page.

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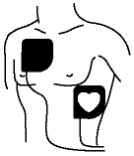
INDICATOR TROUBLESHOOTING TABLE

The following is a troubleshooting table for the AED indicators.

VIEW	SYMPTOM	SOLUTION
	Red **SERVICE** indicator is indicated on screen.	Maintenance by authorized service personnel is required. Call Cardiac Science Customer Service (see page 4) or your local Cardiac Science distributor.
	Red **PADS** indicator is indicated on screen.	Connect the pads or replace with a new pair.
	The battery indicator is red and flashing.	The battery is low. Replace with a new battery.
	STATUS INDICATOR is **RED** and no other indicators on the diagnostic panel are lit.	The battery power is completely depleted. Replace with a new battery. If **STATUS INDICATOR** remains **RED**. Call Cardiac Science Customer Service or your local Cardiac Science distributor.

CAUTION: Temperature Extremes

Exposing the AED to extreme environmental conditions outside of its operating parameters may compromise the ability of the AED to function properly. The RescueReady® daily self-test verifies the impact of extreme environmental conditions on the AED; if the daily self-test determines environmental conditions outside of the AED's operating parameters, a "SERVICE REQUIRED" alert will be issued to prompt the user to move the AED to environmental conditions within the acceptable operating parameters at once. See Section 7 – Technical Data, Parameters, Operation and Standby Conditions.

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SCHEDULED MAINTENANCE

DAILY MAINTENANCE

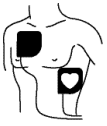
Check the **STATUS INDICATOR** to ensure that it is **GREEN**. When the indicator is **GREEN**, the AED is ready for a rescue. If the indicator is **RED**, refer to the Troubleshooting Table in this chapter.

MONTHLY MAINTENANCE

1. Open the AED lid.
2. Wait for the AED to indicate status:
   Observe the change of the **STATUS INDICATOR** to **RED**. After approximately 5 seconds, verify that the **STATUS INDICATOR** returns to **GREEN**.
3. Check the expiration date on the pads.
4. Listen for the voice prompts.
5. Close the lid and confirm that **STATUS INDICATOR** remains **GREEN**.

ANNUAL MAINTENANCE

Perform the following tests annually to confirm that the diagnostics are functioning properly and to verify the integrity of the case.



Check the Integrity of the Electrodes and Circuitry

1. Open the AED lid.
2. Remove the pads.
3. Close the lid.
4. Confirm that the **STATUS INDICATOR** turns **RED**.
5. Open the lid and confirm that the **PAD** indicator is lit.
6. Reconnect the pads and close the lid.
7. Make sure the expiration date is visible through the clear window of the lid. Check to make sure that the **STATUS INDICATOR** is **GREEN.**
8. Open the lid and confirm that no diagnostic indicators are lit.
9. Check the expiration date of the pads; if expired, replace them.
10. Check the pad's packaging integrity.
11. Close the lid.

Check the Integrity of the Service Indicator and Circuitry

1. Immediately after opening the AED lid, press and hold the **SHOCK** button and confirm that the **SERVICE** is lit.
2. Release the **SHOCK** button.
3. Close the lid.
4. Verify that the **STATUS INDICATOR** remains **RED**.
5. Open the lid and confirm that no diagnostic indicators are lit.
6. Close the lid.
7. Verify the **STATUS INDICATOR** turns **GREEN**.

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Check the Integrity of the Case

Examine the molded case of the AED for any visible signs of stress. If the case shows signs of stress, contact Cardiac Science Customer Service (see page 4) or your local distributor.

Cleaning the AED Case

Gently clean the surface of the AED case with a damp sponge or with a cloth and mild soap.

CAUTION: Case Cleaning Solutions
When disinfecting the case, use a non-oxidizing disinfectant, such as ammonium salts or a glutaraldehyde based cleaning solution, to avoid damage to the metal connectors.

AUTHORIZED REPAIR SERVICE

The AED has no user-serviceable internal components. Try to resolve any maintenance issues with the AED by using the Troubleshooting Table presented in this chapter. If you are unable to resolve the problem, contact Cardiac Science Customer Service (see page 4) or your local distributor.

WARNING: Shock Hazard
Do not disassemble the AED! Failure to observe this warning can result in personal injury or death. Refer maintenance issues to Cardiac Science authorized service personnel.

Note: The warranty will be void upon unauthorized disassembly or service of the AED.

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FREQUENTLY ASKED QUESTIONS

QUESTIONS AND ANSWERS

1. Q: *Can I give CPR while the AED is analyzing?*
   A: No. As with all AEDs, the operator should stop CPR compressions during the analysis phase.

2. Q: *Can I transport the victim while the AED is analyzing?*
   A: No. Vehicle motion may cause noise artifacts that could interfere with proper cardiac rhythm analysis. Stop the vehicle when cardiac rhythm analysis is necessary.

3. Q: *Do I need to prepare the chest prior to pad application?*
   A: Special preparation is not usually necessary. The chest should be as clean, dry, and as oil free as possible. Follow your Medical Director's instruction.

4. Q: *What happens if the battery is low when I begin a rescue?*
   A: When the battery indicator is red, the AED issues a *"Battery Low"* prompt once; however, the AED is still capable of delivering approximately 9 more defibrillation shocks.

   When the AED is not capable of delivering any more shocks, it beeps once every 30 seconds. To continue the rescue attempt, leave the lid open and replace the battery. When the battery replacement takes longer than 60 seconds, the first rescue is terminated and the AED will begin to record the events from then on as a separate rescue.

5. Q: *How do I set the AED internal clock?*
   A: Set the clock by using the RescueLink Software Program and a PC. See Setting the AED Internal Clock in Chapter 3.

6. Q: *What happens if I close the lid in the middle of a rescue attempt?*
   A: If you close the lid during a rescue, you must re-open the lid within 15 seconds to continue the rescue. You will hear the prompt, *"Open Lid to Continue Rescue."* If the lid remains closed for more than 15 seconds, a new rescue will initiate when the lid is reopened.

   Note: If the lid is closed during a rescue while the pads are connected to the patient, the **STATUS INDICATOR** may turn **RED**. When the lid is reopened, however, the rescue may be continued even though the **STATUS INDICATOR** remains **RED**.

7. Q: *My AED is sounding an audible alert. Why? How do I stop it?*
   A: The audible alert indicates that the self-test detected a need for maintenance or corrective action. Determine the maintenance required by using the Troubleshooting Table in this chapter. Opening and closing the lid may turn OFF the audible alert until the next self-test. However, the **STATUS INDICATOR** will remain **RED**.

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8. Q: *The AED did not sound an audible alert when I removed the pads and closed the lid. Why?*
   A: The lid-closed pad self-test only activates the **STATUS INDICATOR**. The AED allows time for replacement of the pads – as removing pads is a normal procedure after a rescue – or a battery during the post rescue procedure, however, an audible maintenance indicator will be triggered after the next Daily Self-Test.

9. Q: *What if I have to perform a rescue in an isolated area and at subzero temperatures?*
   A: When travel to a rescue involves exposing the AED to extremely cold temperatures for an extended period of time, keep the pads and the battery warm.

10. Q: *What should I do if I initiate MANUAL MODE but then decide AED MODE is more appropriate?*
    A: Momentarily closing the lid and opening the lid will always take the device out of MANUAL mode and into AED MODE. Once charging is complete, wait 30 seconds for the AED to revert back to AED MODE. The seconds will count down on the display. If "REMAIN IN MANUAL MODE" has been enabled, momentarily close the AED lid and reopen. This will revert the AED to AED mode.

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SECTION 7 – TECHNICAL DATA

OVERVIEW

This section presents technical data about the AED.

Topic	Page #
Parameters	53
Safety and Performance Standards	56
STAR Biphasic Waveform	59
RHYTHMx ECG Analysis Performance	61

PARAMETERS

OPERATION

Semi-Automatic (shock advisory)
Manual

AUDIBLE ALERTS

Voice Prompt
Maintenance Alert

VISIBLE INDICATORS

STATUS INDICATOR

Display Panel
- BATTERY Indicator
- NUMBER OF SHOCKS DELIVERED Indicator
- ELAPSED RESCUE TIME Indicator
- HEART RATE Indicator
- ECG Display
- PAD PLACEMENT Display, CHECK PADS indicator
- TEXT Display
- CPR Counter
- SERVICE Indicator
- Electrode Indicator
- Manual Mode Indicator
- ECG Monitoring Mode Indicator
- Z-BAR Indicator

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RESCUE DATA STORAGE

Storage	Capacity
Internal	60 minutes ECG data with event annotation

DIMENSIONS

Measurement	Dimension
Height	8 cm (3.3 in)
Width	27 cm (10.6 in)
Depth	31 cm (12.4 in)

WEIGHT

Model	Weight with Batteries and Electrodes
9300P	3.20 kg (7.0 lb)

ENVIRONMENTAL OPERATION AND STANDBY CONDITIONS

Atmosphere	Condition
Temperature	0°C to 50°C (32°F to 122°F)
Humidity	5% to 95% (non-condensing)
Pressure	57kPa (+15,000ft) to 103kPa (-500ft)

SHIPMENT AND TRANSPORT ENVIRONMENTAL CONDITIONS (for up to 1 week)

Atmosphere	Condition
Temperature	-30°C to 65°C (-22°F to 149°F)
Humidity	5% to 95% (non-condensing)
Pressure	57kPa (+15,000ft) to 103kPa (-500ft)

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PADS

- Self-adhesive, disposable defibrillation pads
- Minimum combined surface area: 228cm^2
- Extended length of lead wire: 1.3m

LITHIUM BATTERY SPECIFICATIONS

- Output voltage: 12VDC (max)
- Batteries are non-rechargeable
- Lithium contents: 9.2g (max)
- Check local regulations for disposal information

Model	Estimated Shelf Life (from date of manufacture)	Warranty (from date of installation)	Typical Shocks
9145 Lithium Sulfur Dioxide	5 Years	1 Year or 12 hours of use, whichever occurs first	up to 290 shocks

The battery operating life depends on the type of battery, actual usage and environmental factors.

BATTERIES AND CAPACITOR CHARGE TIMES

A new battery typically takes 10 seconds to charge the AED to maximum energy.

A battery with reduced capacity causes the far left red LED indicator to initially turn ON and typically takes 13 seconds to charge a fully discharged AED to maximum energy.

The maximum time from “Power On” to “Ready to Shock” is 28 seconds for a new rescue.
The maximum time from “Analyze” to “Ready to Shock” is 22 seconds for a new rescue.

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AED SELF-TEST SEQUENCE

Frequency of Self-Test	What is Tested?
Daily	Battery, pads, internal electronics, **SHOCK** button, and software (no charge).
Weekly	Battery, pads, internal electronics, **SHOCK** button, and software (partial charge).
Monthly (every 28 days)	Battery under load, pads, internal electronics, full-energy charge cycle, **SHOCK** button, and software (full charge).
Lid Open (when lid is opened)	Battery, pads, internal electronics, **SHOCK** button, and software.
Lid Closed (when lid is closed)	Battery, pads, internal electronics, **SHOCK** button, and software.

SAFETY AND PERFORMANCE STANDARDS

AED MODEL 9300P

The AED has been designed and manufactured to conform to the highest standards of safety and performance including electromagnetic compatibility (EMC). The Cardiac Science AED Model 9300P and defibrillation pads conform to the applicable requirements of the following:

CE
0086

CE
CE Marked by BSI 0086 per the Medical Device Directive 93/42/EEC of European Union

c ETL LISTED us

ETL
Classified by ETL Semko with respect to electric shock, fire and mechanical hazards only in accordance with UL 60601-1, CAN/CSA C22.2 No.601.1-M90, EN60601-1 and EN60601-2-4. Conforms to UL Standard UL60601-1. Certified to CAN/CSA Standard C22.2 No. 601.1-M90.

Electrical, Construction, Safety and Performance
IEC 60601-1 (1998), Amendments 1 (1991) & 2 (1995)
IEC 60601-2-4 (2002)
ANSI/AAMI DF-39 (1993)

Electromagnetic Compatibility (EMC)
IEC 60601-1-2 (2001)
IEC 60601-2-4 Section 36
ANSI/AAMI DF-39 (1993) Section 3.3.21

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EMISSIONS

Field	Model	Standard or Compliance
E-M	9300P	EN 55011/CISPR 11, Group 1, Class B
Magnetic	9300P	ANSI/AAMI DF39, <0.5mT on surface, except for within 5cm of the lid magnet and the speaker

IMMUNITY

Field	Model	Standard or Compliance
E-M	9300P	IEC 61000-4-3, Level X, (20V/m) IEC 60601-2-4, Section 36.202.3 (20V/m) AAMI DF39, Section 3.3.21.2.1
Magnetic	9300P	IEC 61000-4-8 (2001) IEC 60601-2-4 (2002), Section 36.202.8 AAMI DF39, Section 3.3.21.2.3 80A/m, 47.5Hz – 1,320Hz
ESD	9300P	IEC 61000-4-2, Level 3 IEC 60601-2-4 (2002), Section 36.202.2 6KV contact discharge, 8KV air gap discharge

ENVIRONMENTAL CONDITIONS

Condition	Model	Standard or Compliance
Free Fall Drop	9300P	IEC 60068-2-32 (1975) AM 2 (1990), 1 meter
Bump	9300P	IEC 60068-2-29 (1987), 40g and 6000 bumps
Vibration (Random)	9300P	IEC 60068-2-64 (1993): 10Hz – 2KHz, 0.005 – 0.0012 g^2/Hz
Vibration (Sine)	9300P	IEC 60068-2-6 (1995): 10Hz – 60Hz, 0.15 mm and 60Hz – 150Hz, 2g
Enclosure Protection	9300P	IEC 60529 (2001), IP24

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STORAGE AND SHIPPING CONDITIONS – RECHARGABLE BATTERY

Condition	Standard or Compliance
Shock and Vibration:	The Battery, as installed in the Powerheart AED G3 Pro, meets the following:
Bump:	(IEC 60068-2-29): 40g, 6 ms duration, 1.5 m/s DV, 1000 bumps in each direction.
Random Vibration:	(IEC 60068-2-64): 10hz - 2khz @ 0.005 - 0.0012 g2/Hz.
Transport:	Passes testing per UN "Recommendations of the Transport of Dangerous Goods, Manual of Test and Criteria" (ST/SG/AC.10/11/Rev.3) Addendum 2 (ST/SG/AC.10/27/Add.2)

BATTERY CHARGER

Power Requirements: 90 to 132 VAC or 198 to 264 VAC at 47 to 63 Hz

The Charger operates from, and accepts standard IEC mains power cables.

SHIPPING AND TRANSPORTATION CONDITIONS

ISTA Procedure 2A

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STAR BIPHASIC WAVEFORM

The waveform generated by the Cardiac Science AED is a BIPHASIC TRUNCATED EXPONENTIAL waveform that is compliant with ANSI/AAMI DF2 and DF39. The following is a graph of the waveform voltage as a function of time when the AED is connected to a 50 Ohm resistive load. (See figure A1 and Tables A1 through A3)

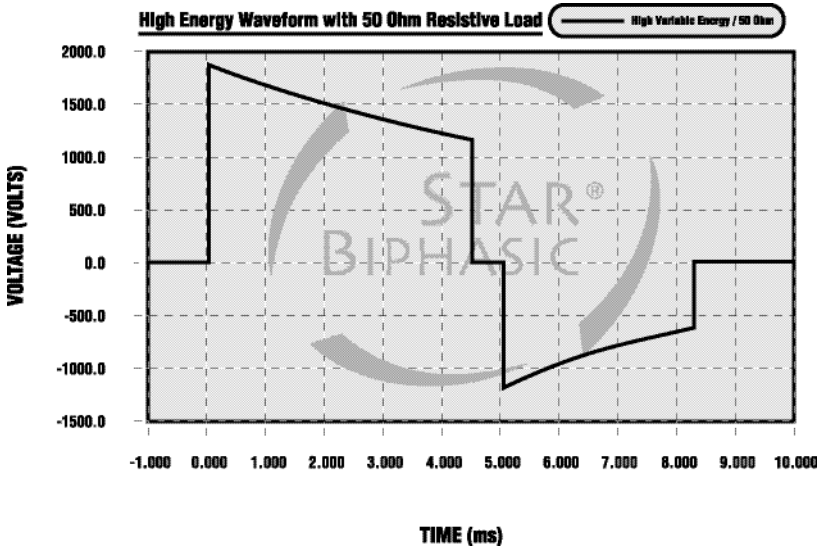

FIGURE A1. STAR BIPHASIC WAVEFORM.

Table A1 - Ultra-Low Current Powerheart AED Models 9300P Waveform (all values are typical)

Patient's Impedance (Ohms)	Phase 1		Phase 2		Energy (Joules)
	Voltage (Volts)	Duration (ms)	Voltage (Volts)	Duration (ms)	
25	1390	3.3	730	3.2	145-195
50	1420	4.5	915	3.2	130-175
75	1430	5.8	980	3.2	120-160
100	1435	7.0	1020	3.2	110-150
125	1440	8.3	1040	3.2	105-140

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Table A2 - Low Variable Energy Powerheart AED Models 9300P Waveform (all values are typical)

Patient's Impedance (Ohms)	Phase 1		Phase 2		
	Voltage (Volts)	Duration (ms)	Voltage (Volts)	Duration (ms)	Energy (Joules)
25	1570	3.3	825	3.2	200-250
50	1600	4.5	1030	3.2	170-210
75	1610	5.8	1105	3.2	120-160
100	1615	7.0	1150	3.2	150-180
125	1620	8.3	1170	3.2	140-170

Table A3 - High Variable Energy Powerheart AED Models 9300P Waveform (all values are typical)

Patient's Impedance (Ohms)	Phase 1		Phase 2		
	Voltage (Volts)	Duration (ms)	Voltage (Volts)	Duration (ms)	Energy (Joules)
25	1885	3.3	990	3.2	265-360
50	1920	4.5	1240	3.2	235-320
75	1930	5.8	1325	3.2	215-295
100	1940	7.0	1380	3.2	200-270
125	1945	8.3	1405	3.2	190-260

ENERGY LEVELS AND PATIENT IMPEDANCE

The Cardiac Science Biphasic Truncated Exponential (BTE) waveform utilizes variable energy. The actual energy delivered will vary with the patient's impedance and the device will deliver a shock when impedance is between 25-180 Ohms. Energy will be delivered at three different levels referred to as ultra-low variable energy, low variable energy, and high variable energy as shown in the above waveform tables.

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RHYTHMx ECG ANALYSIS PERFORMANCE

The AED RHYTHMx ECG Analysis system analyzes the patient's ECG and advises you when the AED detects a shockable or non-shockable rhythm.

This system makes it possible for a person, with no training in the interpretation of ECG rhythms, to offer defibrillation therapy to victims of sudden cardiac arrest.

CARDIAC RHYTHMS USED TO TEST THE RHYTHM RECOGNITION DETECTION SYSTEM FOR CARDIAC SCIENCE AED

Rhythm Class	Specifications
Shockable Rhythm – VF	Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity[a] of >90%
Shockable Rhythm – VT	Meets AAMI DF 39 requirement and AHA recommendation of Sensitivity of >75%
Non-Shockable Rhythm – NSR	Meets AAMI DF 39 requirement (>95%) and AHA recommendation (>99%) of Specificity
Non-Shockable – Asystole	Meets AAMI DF 39 requirement and AHA recommendation of Specificity of >95%
Non-Shockable – all other rhythms	Meets AAMI DF 39 requirement and AHA recommendation of Specificity of >95%

[a] *Automatic External Defibrillators for Public Access Defibrillation: Recommendations for Specifying and Reporting Arrhythmia Analysis Algorithm Performance, Incorporating New Waveforms and Enhancing Safety, AHA AED Task Force and approved by the AHA Science Advisory and Coordinating Committee. Circulation, 1997(95), pp 1677-1682*

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SECTION 8 – MDLINK

OVERVIEW

MDLink software enables the Medical Director to modify several preprogrammed operational parameters and to define User Identifiers for Automated External Defibrillators (AEDs) and associated battery packs manufactured by Cardiac Science, Corp.

Topic	Page #
MDLINK INSTALLATION	64
ESTABLISH CONNECTION FROM THE AED TO THE COMPUTER	65
SELECTABLE OPTIONS PARAMETERS	68
COMMAND BUTTONS	71

- Some features described in this manual may not apply to your AED.
- MDLink is not used with FirstSave G3 AEDs.
- The user may choose from program options that tailor the AED to meet the specific needs and requirements of the user. This manual describes how to install, start, and use MDLink.

CAUTION:
The AED is programmed with software that has been tested to work with versions of RescueLink and MDLink that are included with the AED. When older versions of RescueLink and MDLink are used to communicate with this AED, there may be features described in this manual that are not available. Also, when communicating with an older AED with the version of RescueLink and MDLink included with this new AED there may be features described in this manual that cannot be used. The software in most cases will give an error message when incompatibilities occur.

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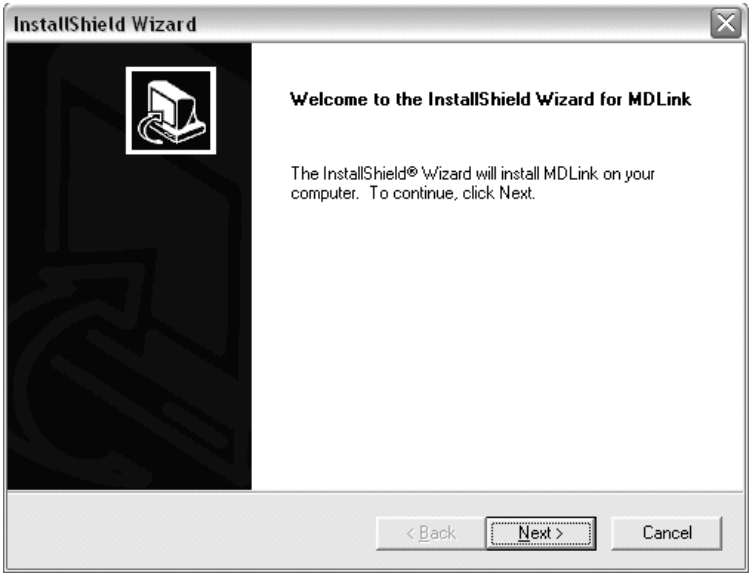
MDLINK INSTALLATION

MDLink is compatible with Windows 98, 2000, and XP

To install MDLink, perform the following steps:

1. To install MDLink, put the QuickStart Tool Kit CD-ROM in the CD drive. The program will Autorun.
2. Follow the instructions on the MDLink page to download the MDLink software.
3. After the MDLink Welcome screen appears, click Next to initiate the installation process.
4. Follow the "InstallShield Wizard" to complete the installation.


InstallShield Wizard
Welcome to the InstallShield Wizard for MDLink
The InstallShield® Wizard will install MDLink on your computer. To continue, click Next.
< Back
Next >
Cancel

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ESTABLISH CONNECTION FROM THE AED TO THE COMPUTER

A connection must be established between the AED and the PC to send and/or receive MDLink settings.

FOR INFRARED (IR) CONNECTION:

1. Install the IR dongle as directed to the appropriate Com Port on the PC.
2. Open the lid of the AED.
3. Place the AED with the IR port facing the eye of the IR dongle about 1-3 feet from the IR eye. If the connection is not established, shield the connection and/or move the IR eye closer.

The AED lid must be opened to transfer the parameters.

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STARTING MDLINK

With the connection established between the AED and the PC the AED will speak "COMMUNICATIONS MODE"

- Double-click the MDLink icon that was placed automatically on your PC desktop during installation; or
- Double-click the **MDLink.exe** file. The file can be found in the installation directory specified during the installation process.

A password is required to use the MDLink software program. The software requires you to use the preset password, or one you choose, each time MDLink is run. Type the preset password RESCUE and click OK.

The password may be changed to limit access to the MDLink software. Change the preset password on the MDLink main screen by using the Password command button as described in the Command Buttons section of this chapter.

After entering the password, the MDLink screen appears and all available parameters are displayed. See next page.

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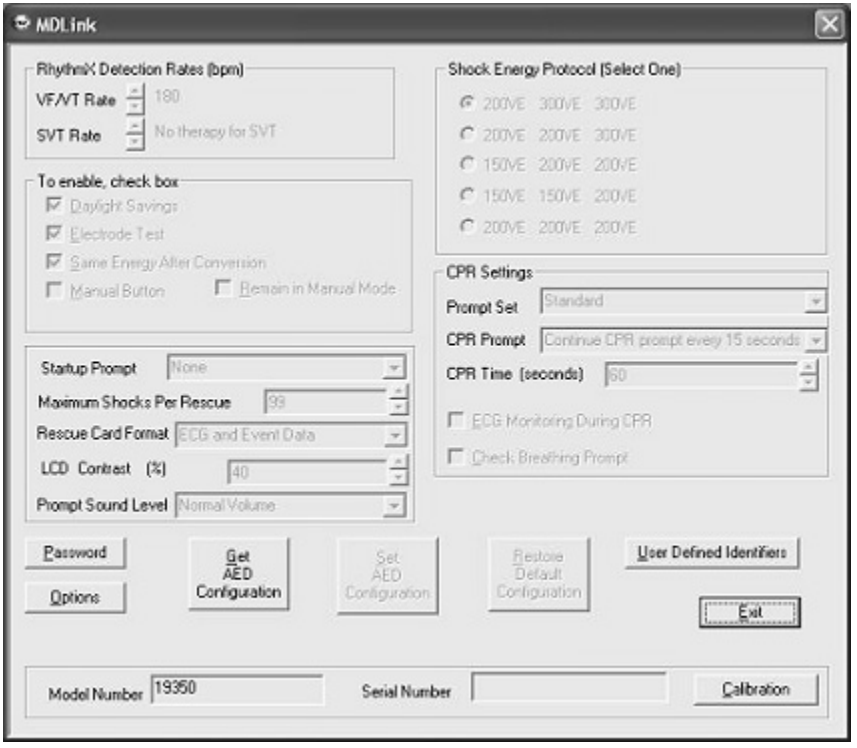
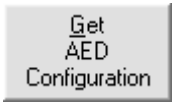


To confirm the settings of your specific AED, click on "GET AED CONFIGURATION"

GET AED CONFIGURATION



The Get AED Configuration command allows you to retrieve the parameters from the internal memory of the AED. When retrieving the parameter from the internal memory of the AED, click **Get AED Configuration** to get the stored parameters from the desired location. The internal parameters, model number and serial number of the AED will appear on the **MDLink** screen.

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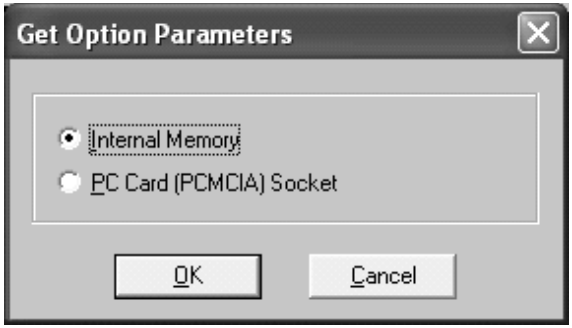

Note: The PC Card (PCMCIA) socket option only applies to 9110 and 9210 series AEDs and is not available in the 9300 series AEDs.

SELECTABLE OPTIONS PARAMETERS

OPTION DEFAULTS

By using the MDLink software with a PC, the user may modify the AED parameters listed in the following table. To change the option defaults, use the up/down arrows, radio buttons and check boxes next to the functions to select the desired option. Choose all the parameters and then click the Set AED Configuration command to simultaneously store all of the selected parameters.

Not all of the following functions may be available for your AED. This will depend on the model of your AED.

FUNCTION	DEFAULT	SELECTABLE OPTIONS
VF/ VT Rate	160 bpm	120 to 240 bpm
SVT Rate	No Therapy for SVT	160 to 300 bpm; or No Therapy for SVT
Shock Energy Protocol	200VE, 300VE, 300VE	Ultra Low VE Standard (Low or High) VE; Non-escalating low VE
Daylight Savings	Enabled	Enabled, Disabled
Electrode Test	Enabled	Enabled, Disabled
Same Energy After Conversion	Enabled	Enabled, Disabled
Manual Button	Enabled	Enabled, Disabled
Remain in Manual Mode	Disabled	Enabled, Disabled
CPR Mode	Metronome Sound	No Sound; Continue CPR Prompt; Beep; or Metronome sound
Rescue Data Card[1]	ECG & Event Data	ECG & Event Data; or ECG, Event Data and Voice Recording
LCD Contrast	40%	0% to 100%
Maximum Shocks Per Rescue	99	3 to 99
CPR Time (seconds)	120	60 to 180

[1]This feature only applies to 9110 and 9210 series AEDs and is not available in the 9300 series AEDs.

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RHYTHMX DETECTION RATES - VF/VT AND SVT RATES

The Detection Rates for VF/VT and SVT can be programmed by the Medical Director using the MDLink software. All rhythms with rates between the VF/VT Rate and SVT Rate will be screened through SVT discriminator criteria in order to classify the patient's rhythm as VF/VT or SVT. Based on the VF/VT Rate setting, all ventricular fibrillation (VF) and ventricular tachycardia (VT) rhythms at or above the set rate will be classified as shockable. All rhythms below the set VF/VT Rate will be classified as non-shockable. The default VF/VT Rate is 160 bpm (beats per minute), with selectable rates between 120 bpm and 240 bpm.

SVT Rate is designed to reduce the risk of shocking a SVT rhythm based on rate alone, by differentiating between SVT and VT rhythms. The default SVT Rate is "No Therapy for SVT", with selectable rates between 160 to 300 bpm or "No Therapy for SVT." Rhythms at or above the selected SVT Rate will be classified as shockable. The SVT Rate must be set greater than or equal to the VF/VT Rate. If "No Therapy for SVT" is selected, the AED will not advise defibrillation therapy if a SVT rhythm is present.

SHOCK ENERGY PROTOCOL

The AED follows guidelines recommended by the American Heart Association (AHA) and the International Liaison Committee on Resuscitation (ILCOR). Upon detecting a shockable cardiac rhythm, the AED advises the user to press the "Shock" button to deliver a defibrillation pulse followed by the user performing CPR. Using the MDLink option, the energy protocol for the AED can be programmed with one of the following protocols:

AED SHOCK ENERGY PROTOCOLS

DESCRIPTION	1ST SHOCK	2ND SHOCK	3RD SHOCK
Ultra Low Energy A	150 VE	150 VE	200 VE
Ultra Low Energy B	150 VE	200 VE	300VE
Standard (High - Default Value)	200 VE	300 VE	300 VE
Standard (Low)	200 VE	200 VE	300 VE
Non-Escalating Low Energy	200 VE	200 VE	200 VE

DAYLIGHT SAVINGS

The AED contains an internal clock that will automatically adjust for Daylight Savings Time. The internal clock will adjust forward one hour when Daylight Savings Time becomes effective and backward on hour when Standard Time becomes effective.

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ELECTRODE TEST

As part of the daily self-test, the AED will check for properly connected electrodes. Only electrodes approved by Cardiac Science are intended to be used with the AEDs.

⚠ ***CAUTION*: Possible Improper Device Performance**
Use of any electrodes other than those approved by Cardiac Science may cause the AED to function improperly during a rescue. The use of other brands of electrodes, other than those approved by Cardiac Science, may void the Cardiac Science Limited Warranty.

SAME ENERGY AFTER CONVERSION

The AED delivers the same energy level as was delivered in the previous defibrillation pulse after a patient has converted from ventricular fibrillation (VF) or ventricular tachycardia (VT) to normal sinus rhythm (NSR) and back again to VF or VT.
To allow the AED to increment the energy level of the defibrillation pulse delivered after conversion, click the box to the left of the **Same Energy after Conversion** to disable. This does not apply if the previous defibrillation pulse used is the high variable energy level (300VE).

MANUAL BUTTON

The user may disable the manual override functionality in model 9300P. If the user attempts to use this feature when disabled, a NO MANUAL BUTTON symbol will appear in the display. This feature is intended for advanced medical personnel with the ability to differentiate between shockable and non-shockable cardiac rhythms.

REMAIN IN MANUAL MODE

With Remain In Manual Mode enabled and the user enters manual mode, the AED will remain in the manual mode. Further AED rhythm analysis, and CPR prompting are disabled when "Remain in Manual Mode" is enabled.

CPR MODE

The user may select a metronome sound, "Continue CPR" verbal prompt (repeats every 30 seconds), beep tone (repeats every 30 seconds) or no sound.

RESCUE DATA CARD

This feature only applies to 9110 and 9210 series AEDs and is not available in the 9300 series AEDs.

MAXIMUM SHOCKS PER RESCUE

The AED is capable of delivering up to 99 defibrillation shocks per rescue attempt (A rescue attempt is defined as the time when the electrodes are placed on the chest of the patient until the lid is closed and the device powers down).

CPR TIME

After a shock is delivered or detection of a non-shockable rhythm, the AED automatically enters CPR mode. The AED default CPR Time setting is 120 seconds. The CPR time setting can be set to a minimum of 60 seconds to a maximum 180 seconds, in increments of 1 second.

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LCD CONTRAST (APPLIES TO "PRO" MODEL ONLY)

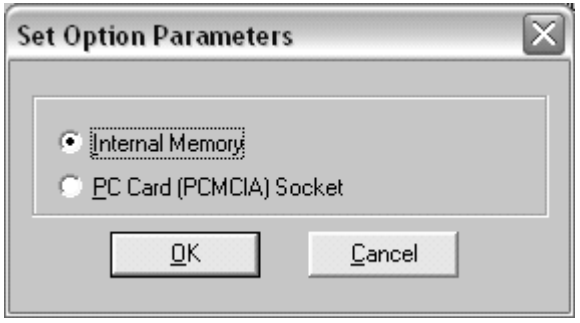
Provides contrast adjustment for maximum visibility of the Color Display Screen

COMMAND BUTTONS

The command buttons may be selected by clicking the desired button; or holding down the Alt key and typing the key of the underlined character in the command name.

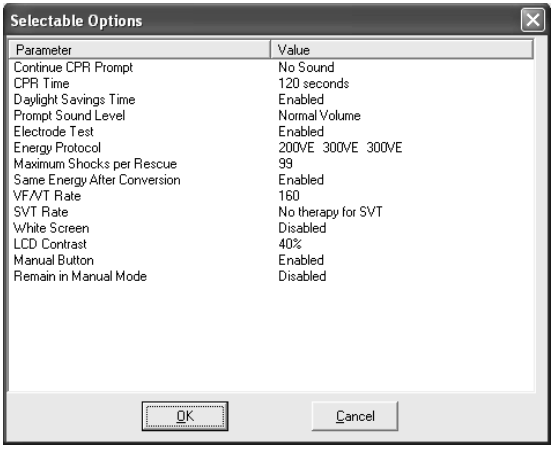
SET AED CONFIGURATION

The Set AED Configuration command allows you to store the selected parameters in the internal memory of the AED. Set the desired values for all parameters and then click **Set AED Configuration** to store the selected parameters to the AED.



The PC Card (PCMCIA) socket option only applies to 9110 and 9210 series AEDs and is not available in the 9300 series AEDs.

Before the selected parameters are stored, the **Selectable Options** screen allows you to review all the parameters. If the parameters are correct, click **OK**. Click **Cancel** to return to the **MDLink** screen.



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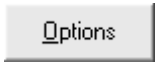
After the desired location has been successfully updated with the selected parameters, click **OK** to return to the **MDLink** screen.

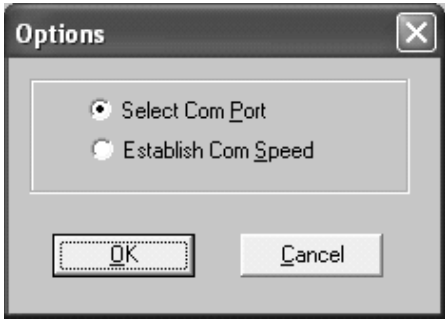
OPTIONS

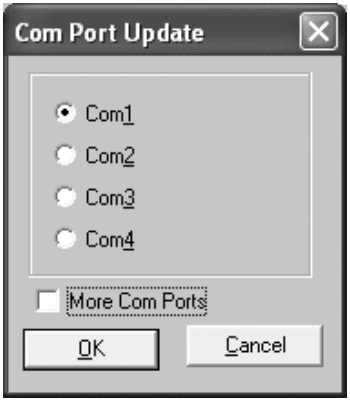


The Options command allows you to select the communications port; or establish the communication speed. The Options screen will appear when the **Options** command is selected.

SELECT THE COMMUNICATIONS PORT

Select Com Port allows you to change the Com Port selected during installation. Choose **Select Com Port** and click **OK**.





Select the communications port that the PC will be using to transfer data to or from the AED. If using a USB-Com adapter, select the check box **More Com Ports** for Com Port options Com5 and Com8. Click OK and MDLink returns to the **MDLink** screen.

The Com Port changes affect only the current MDLink session. The Com Port specified during installation will be used the next time MDLink is executed.

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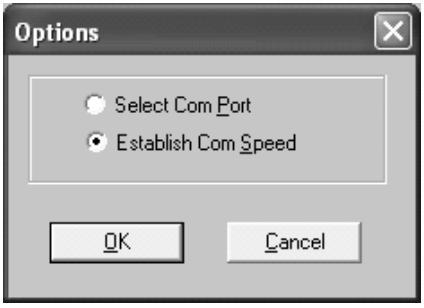
ESTABLISH COMMUNICATION SPEED

The AED and the PC will automatically find a compatible data transfer speed the first time MDLink is used. Establish Com Speed may be used to verify that communications are functioning properly. Use of this command will be rare. Select **Establish Com Speed** and click **OK**.



The data transferal speed between the PC and the AED is established and MDLink returns to the **MDLink** screen.

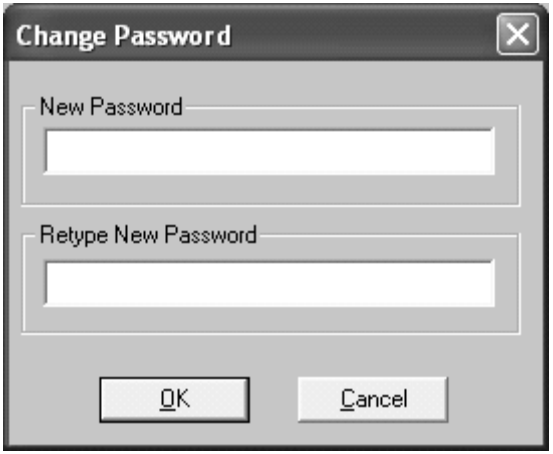
PASSWORD

The Password command allows you to change the preset password.

Select the **Password** command button.

Type in the new password. Any keystroke is a valid password character. As you type, the characters appear as asterisks (*).

To confirm the new password, re-type the new password and click **OK**.



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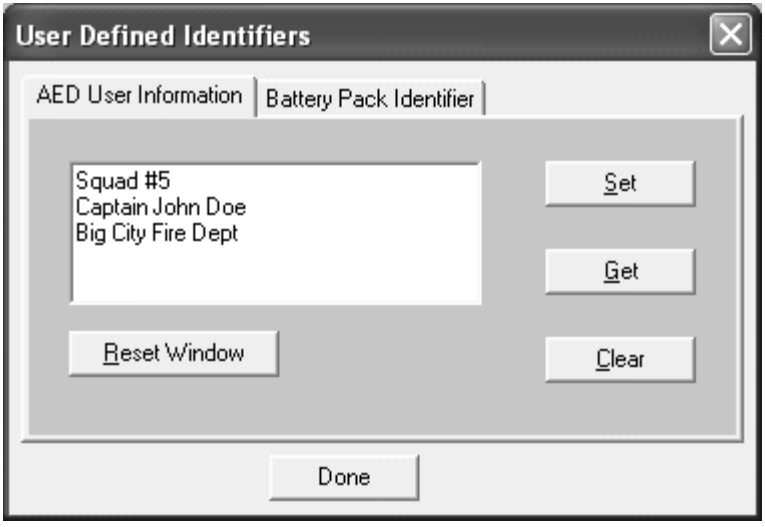
A message will display confirming that the preset password has been changed. If you did not type the password correctly the second time, you will be asked to re-enter the password.

USER DEFINED IDENTIFIERS

The User Defined Identifiers option allows for the user to define identification information for the AED or the currently installed IntelliSense battery.

AED USER INFORMATION

This screen allows the user to define AED identification information. You may type up to 45 characters of device identification information to be stored within the internal memory of the AED. This information is archived with each rescue attempt and will be displayed with RescueLink rescue data.



- **To retrieve identification information** from the internal memory of the AED, click the Get button and the information will appear in the screen.

- **To enter new or change existing AED identification information:** type the information onto the screen and click **Set** to store the information in the internal memory of the AED.

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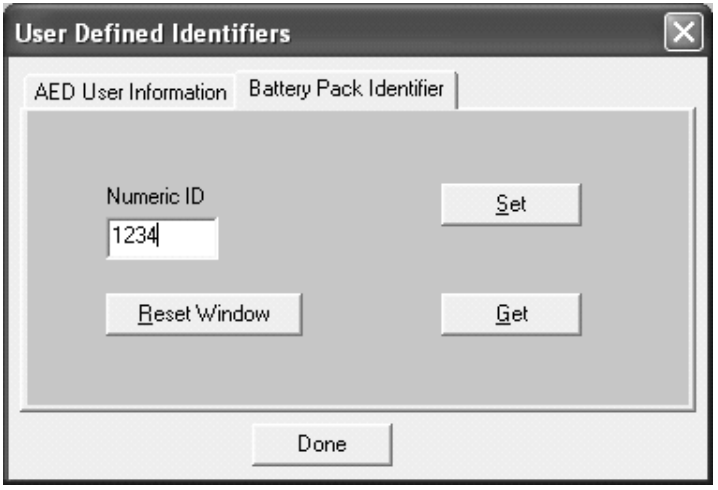
- **To erase AED identification information:** click on **Clear** and the identification information will be erased from within the AED.

- **To clear the text box:** click the **Reset Window** button. This does not affect the information stored in the AED.

Use the **Done** button to return to the **MDLink** screen.

INTELLISENSE BATTERY PACK IDENTIFIER

The Battery Pack Identifier screen allows the user to give the battery an identifier number. Any number from 1 to 65,000 may be entered and stored within the memory of the IntelliSense battery. This information is archived with each rescue attempt and will be displayed with RescueLink rescue data.



- **To retrieve battery identification information:** click on the **Get** button and the identification number (if specified) will appear in the screen.

MDLink will prompt you if the battery has not been assigned an identification number.

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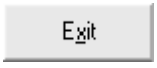
- **To enter a new identification number:** type the information onto the screen and click Set to store the information in the battery memory. If the battery already contains an identifier, MDLink will allow you to cancel the **Set** command or overwrite the current identifier.

- **To clear the Numeric ID text box:** click **Reset Window**. This does not affect the information stored in the battery.

Use the **Done** button to return to the **MDLink** screen.

EXIT



When you are finished using MDLink, select the **Exit** command to close the program.

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